COULTER® GEN•S™ System

Reference

PN 4237221C (Dec 1999)

COULTER CORPORATION
Miami, Florida 33196

READ ALL PRODUCT MANUALS AND CONSULT WITH COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING-Might cause injury.
CAUTION-Might cause damage to the instrument.
IMPORTANT-Might cause misleading results.

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Coulter into your computer. Only operate your system's computer with software authorized by Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

Coulter Corporation urges its customers to comply with all national health and safety standards such as the use of barrier protection. This may include, but it is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

WARNING Risk of operator injury if all covers are not secured in place prior to instrument operation or you attempt to replace a part without carefully reading the replacement instructions. Do not attempt to replace any component until you carefully read the instructions for replacing the component.

IMPORTANT If you purchased this product from anyone other than Coulter or an authorized Coulter distributor, and, if it is not presently under a Coulter service maintenance agreement, Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Coulter Representative.

REVISION STATUS

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Software Version 2C. Updated illustrations an pages 3-8 and 5-2 to reflect new Laser Warning Labels.

This document applies to the latest software listed and higher versions. When a subsequent version changes the information in this document, a new issue will be released.

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This introductory section contains the following topics:

- How to use your COULTER GEN•S System hard-copy manuals
- About this manual
- Online Help System
- Conventions
- Documentation available

HOW TO USE YOUR COULTER® GEN•S™ SYSTEM HARD-COPY MANUALS

Use the Getting Started booklet to see an overview of the system hardware and software. This document comes with your GEN•S System.

Use the Reference manual for in-depth information about what the instrument does, the methods it uses, its specifications, and information on installation, safety and software options. The Reference manual for the GEN•S System is included online; it is available in hard copy by request.

Use the Special Procedures and Troubleshooting manual to run calibration; to clean, replace or adjust a component on the instrument; and for troubleshooting. This document is made up of procedures from the online Help system; it is available in hard copy by request.

Use the Operator's Guide for the day-to-day operation of your instrument. This document is made up of procedures from the online Help system; it includes Startup, running controls and samples, reviewing data, Shutdown, and the software on the Analyzer and the Workstation. This document is available in hard copy by request.

Use the Master Index to easily locate a subject in your hard-copy Reference manual, Operator's Guide or Special Procedures and Troubleshooting manual. The Master Index comes with the hard copy of both the Operator's Guide and the Special Procedures and Troubleshooting manual.

Use the Host Transmission Specification to find the information needed to program the transmission interface between the GEN•S System and your laboratory's host computer. This document comes with your GEN•S System.

See the Documentation page on the back cover of this manual for the contents of each manual. It can help you to determine quickly in which manual the information you need is located.

ABOUT THIS MANUAL

Your GEN•S System Reference manual is a source of information on what the system does.

This information is organized as follows:

- Chapter 1, Use and Function
  Contains the intended use of the instrument, a brief history of the methods used, the reagents, calibrators and controls used, and a short description of the major components.
- Chapter 2, Installation
  Contains the instrument requirements, and the diagrams of the reagent/pneumatic

tubing connections and the interunit cable connections.

- Chapter 3, Operation Principles
  Contains descriptions of the Coulter Method, the normal sample flow through the instrument, how counting and sizing are accomplished, and what the DataPlots show.
- Chapter 4, Specifications/Characteristics
  Details the instrument and performance specifications, the performance characteristics, the interfering substances, and the bar-code label specifications.
- Chapter 5, Precautions/Hazards
  Describes laser safety precautions and the location of the laser-related labels.
- References
- Glossary
- Index, hard copy only

ONLINE HELP SYSTEM

The GEN•S Workstation has a comprehensive Online Help System, which includes this Reference manual, plus all operating, maintenance and troubleshooting procedures, assistants, and CBT tutorials. On the GEN•S Workstation, select to access Help. Select to access the tutorials.

CONVENTIONS

This document uses the following conventions:

indicates a key on the Diluter keypad.

indicates a key on the GEN•S Workstation keyboard.

is the icon for Patient results on the GEN•S Workstation.

is the icon for the Printer on the GEN•S Workstation.

Book is the button you select in the online Help system for the Reference manual.

1.1 INTENDED USE

The COULTER® GEN•S™ System, Figure 1.1, is a quantitative, automated hematology analyzer For In Vitro Diagnostic Use in clinical laboratories. The GEN•S System provides automated complete blood count, leukocyte differential and Reticulocyte analysis.

The purpose of the GEN•S System is to separate the normal patient, with all normal system-generated parameters, from the patient who needs additional studies of any of these parameters. These studies might include further measurements of cell size and platelet distribution, biochemical investigations, manual WBC differential or any other definitive test that helps diagnose the patient's condition.

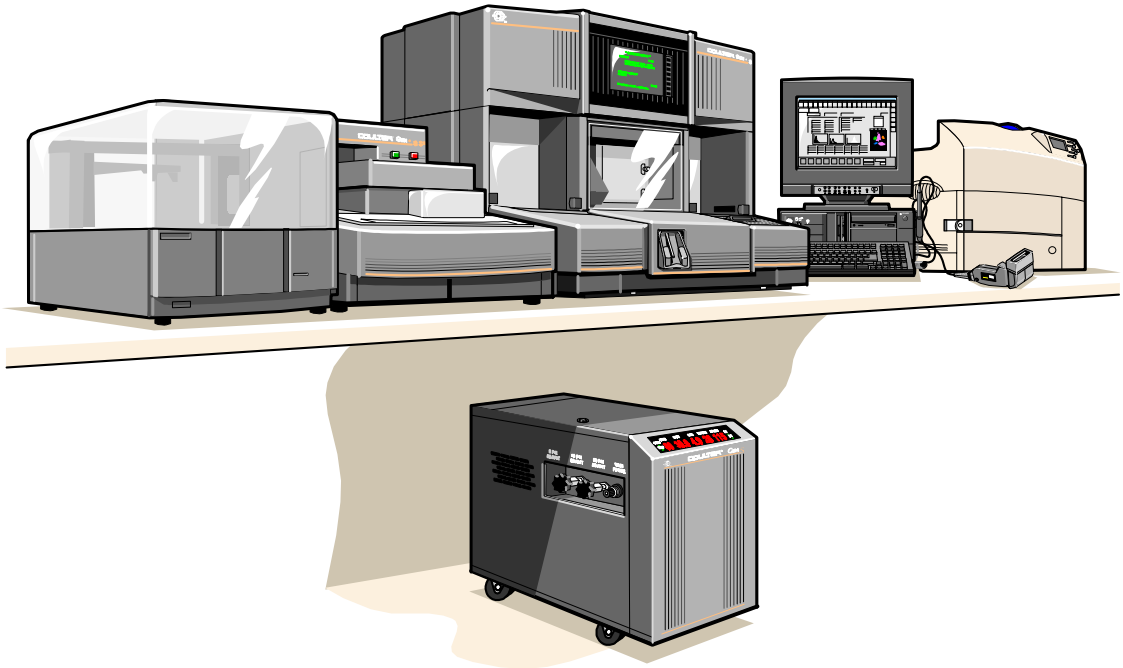

Figure 1.1 COULTER GEN•S System

Note: Although shown in Figure 1.1, the SlideMaker and SlideStainer were not available at the time of the GEN•S System product release.

Parameters

The system determines these hematologic parameters of whole-blood specimens:

WBC	White Blood Cell or leukocyte count
RBC	Red Blood Cell or erythrocyte count
Hgb	Hemoglobin concentration
Hct	Hematocrit (relative volume of erythrocytes)
MCV	Mean Corpuscular (erythrocyte) Volume
MCH	Mean Corpuscular (erythrocyte) Hemoglobin
MCHC	Mean Corpuscular (erythrocyte) Hemoglobin Concentration
RDW	Red Cell (erythrocyte volume) Distribution Width
Plt	Platelet or thrombocyte count
MPV	Mean Platelet (thrombocyte) Volume
LY%	Lymphocyte percent
MO%	Monocyte percent
NE%	Neutrophil percent
EO%	Eosinophil percent
BA%	Basophil percent
LY#	Lymphocyte number
MO#	Monocyte number
NE#	Neutrophil number
EO#	Eosinophil number
BA#	Basophil number
RET%	Reticulocyte percent
RET#	Reticulocyte number
*HLR%	High Light scatter Reticulocytes %
*HLR#	High Light scatter Reticulocytes #
*IRF	Immature Reticulocyte Fraction
*MRV	Mean Reticulocyte Volume
*MSCV	Mean Sphered Cell Volume
*Pct	Plateletcrit
*PDW	Platelet Distribution Width

*For Research Use Only. Not For Use In Diagnostic Procedures.

Unless otherwise stated, all parameter results are shown in a US unit format throughout the manuals.

1.2 QUALITY CONTROL (QC)

Your laboratory can use these QC techniques with the GEN•S System:

- Daily instrument checks
- Commercial controls
- Delta checks
- Patient controls
- Analysis
- Interlaboratory Quality Assurance Program (IQAP)

Quality Assurance includes routine maintenance and service in conjunction with the use of controls and calibrators. The combination of these methods provides the assurance of complete quality control and should be applied separately or in combination, in accordance with your laboratory, state and federal protocols.

1.3 METHOD HISTORY

Development

W.H. Coulter (1956) describes the Coulter Principle:[1]

> A suspension of blood cells is passed thru [sic] a small orifice simultaneously with an electric current. The individual blood cells passing thru the orifice introduce an impedance change in the orifice determined by the size of the cell. The system counts the individual cells and provides cell size distribution. The number of cells counted per sample is approximately 100 times greater than the usual microscope count to reduce the statistical error by a factor of approximately 10 times.

This substantial improvement in precision over previous methods helped to establish the erythrocyte count as a sensitive index of erythropoietic dyscrasia, particularly when considered together with Hct and Hgb measurements.[2]

The COULTER COUNTER® Model S analyzer was the first instrument that automated simultaneous multiparameter measurements on blood. Brittin et al., Gottmann, and Hamilton and Davidson, reviewed the performance and clinical value of the Model S.[3] [4] [5]

Refinements of the COULTER COUNTER analyzer to provide accurate size (volume) distribution data led to a reawakening of interest in pathological erythrocyte size distribution, first sparked by Price-Jones.[6] [7]

Among the advantages offered by the Coulter method of counting and sizing was the ability to derive an accurate Hct measurement by summing the electronic volume of erythrocytes. England et al. speculated that electronic Hct measurements did not contain the trapped plasma error of centrifugal Hct measurements.[8]

Bull et al. described the use of a COULTER COUNTER analyzer for counting thrombocytes.[9] This method, useful as it was, depended on preparing thrombocyte-rich plasma to avoid counting erythrocytes as thrombocytes. Mundschenk et al. and Schulz and Thom discussed the possibility of counting thrombocytes in the presence of erythrocytes and classifying them by size.[10] [11] Electronic refinements in the Model S-PLUS enhanced the accuracy of the hydrodynamic method. Von Behrens and Paulus have also cited the feasibility of counting thrombocytes by the Coulter method.[12] [13]

Hemoglobinometry

The lytic reagent used for the complete blood count (CBC) parameters prepares the blood so the system can count leukocytes and measure the amount of hemoglobin. The lytic reagent rapidly and simultaneously destroys the erythrocytes and converts a substantial proportion of the hemoglobin to a stable pigment while it leaves leukocyte nuclei intact. The absorbance of the pigment is directly proportional to the hemoglobin concentration of the sample.

The accuracy of this method equals that of the hemiglobincyanide method, the reference method of choice for hemoglobinometry recommended by the International Committee for Standardization in Hematology.[14]

Differential Measurement

The COULTER VCS established WBC differential technology using three measurements: individual cell volume, high-frequency conductivity and laser-light scatter.

The combination of low-frequency current, high-frequency current and light-scattering technology provides abundant cell-by-cell information that is translated by the instrument into conventional stained-film leukocyte categories.

Volume Analysis

Electronic leukocyte volume analysis, using low-frequency current, has been used since 1967.[15] It has been evaluated as a possible adjunct to the differential white cell count.[16 17 18 19]

Conductivity Analysis

Cell walls act as conductors to high-frequency current. The current, while passing through the cell walls and through each cell interior, detects differences in the insulating properties of cell components. The current characterizes the nuclear and granular constituents and the chemical composition of the cell interior.[20 21 22]

Light Scatter Analysis

Coulter's experience in flow cytometry dates back decades to Fulwyler's pioneering use of light scatter for cell analysis.[23] Loken et al. and Jovin et al. discuss the relationship of particle size and refractivity to the angle of light scattered from a laser beam.[23 24 25]

Reticulocyte (Retic) Analysis

Reticulocytes are immature, nonnucleated erythrocytes retaining a small network of basophilic organelles, consisting of RNA and protoporphyrin. The enumeration of reticulocytes provides a simple, effective means to determine red cell production and regeneration.[26 27 28 29]

The most common means of measuring reticulocytes is to use supravital dyes , such as New Methylene Blue or Brilliant Cresyl Blue. These dyes precipitate and aggregate the basophilic substances within the reticulocyte, resulting in a granular, staining pattern easily seen with light microscopy.[30]

COULTER IntelliKinetics™ Application

The GEN•S System introduces the COULTER IntelliKinetics application. Control of reaction kinetics is extremely important to ensure the best performance of the automated white cell differential and reticulocyte analysis. The IntelliKinetics application is a management tool for the key step of system optimization when fluctuations in external variables in the laboratory, such as temperature, occur.

The IntelliKinetics application management ensures consistent reaction kinetics. This application intelligently manages variations in ambient laboratory temperature through automatic adjustments to reagent reaction temperature, exposure time and delivery volumes. Enhancements in instrument electronics, such as improved signal-to-noise ratio, work with the IntelliKinetics application to provide better data signals for the system algorithms to analyze. Reagent temperature control helps to increase the speed of dye uptake, thereby improving instrument throughput. Analysis occurs under controlled conditions.

The GEN•S System with the IntelliKinetics application shows improved separation of populations, both for the white cell differential and reticulocytes. Cell populations made available for analysis by the algorithms are in a more consistent location in three-dimensional space. The IntelliKinetics application, working in concert with new algorithms, provides the instrument with the best signals for analysis, even when the laboratory environment varies throughout the day.

$\bar{x}_B$ Analysis

Dennis B. Dorsey, MD, proposed in 1963 that the relatively constant blood cell indices could be used to follow the performance of hematology instrumentation.[31]Brian Bull, MD, improved the technique and it is termed $\bar{x}_B$ Analysis.[32]

$\bar{x}_B$ Analysis uses a "weighted moving average" of patient sample results because Koepke and Protextor said that QC materials "ideally should be similar in structure and in reactivity to the patient constituent being measured. Therefore freshly drawn patient blood samples seem to be the most appropriate [QC material]."[33] Bull explains, "The analyser [sic] is considered to be 'in control' when mean MCV, MCH, and MCHC determined on a batch of 20 patients by use of the algorithm $\bar{x}_B$ are within 3% of the expected mean indices of the population."[34]

1.4 SYSTEM COMPONENTS

The GEN•S System is a modular system that consists of the following units.

Power Supply

This unit consists of two assemblies. The Electronic Power Supply assembly provides the regulated and unregulated voltages required by the circuitry of the system. The Pneumatic Power Supply assembly is the source of air pressure and vacuum.

Diluter

This unit is the primary operating unit of the system. It performs the mixing, transporting, pipetting, diluting, lysing, and sensing functions. Many of the controls and indicators needed for normal daily operation are on the front of the Diluter.

Analyzer

This unit controls the electronic sequence of each operating cycle and calculates the results. It receives count and size information directly from the Diluter while the sample is being cycled; then it counts, measures, and computes the parameters. The Analyzer then sends this information to the Workstation.

GEN•S Workstation

The GEN•S Workstation holds the data algorithms used to process the List Mode Data supplied by the Analyzer. From the List Mode Data, the Workstation computes Diff and Retic results, develops the histograms and DataPlots, and displays the results. The Workstation stores the data and transmits it to the Printer and Host computer.

The GEN•S Workstation is equipped with a light pen that allows operator interaction with the software.

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Coulter into your computer. Only operate your system's computer with software authorized by Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

The GEN•S Workstation is not for use as a general purpose personal computer.

Handheld Scanner

Use the handheld scanner to manually read bar-code labels.

1.5 HARDWARE OPTIONS

Graphic/Laser Printer

You can use any printer that is supported by the Microsoft® Windows NT™ operating system. The Printer prints the data displayed on the GEN•S Workstation screen, including parameter data and graphics.

GEN•S Workstation Touch Screen

The touch screen allows operator interaction with the software by touching the screen.

GEN•S SM™ Integrated Slidemaker‡

The GEN•S SM Integrated Slidemaker makes blood smears from samples as they are being analyzed, according to user-defined criteria. This option will be available at a later date.

1.6 CONTROLS AND CALIBRATOR

Controls

Use stable reference controls to monitor the instrument performance as part of your quality control and to verify calibration. Refer to the package insert for detailed information before using a control.

COULTER 5C cell control monitors the CBC and differential (Diff) parameters.

COULTER LATRON primer prepares the tubing and instrument components for the LATRON control.

COULTER LATRON control monitors the performance of the volume, conductivity and light scatter measurements.

COULTER Retic-C cell control monitors the reticulocyte (Retic) parameters.

Calibrator

The COULTER S-CAL® calibrator kit is an acceptable alternative to the whole-blood reference method of calibration. S-CAL calibrator is traceable to reference methods and materials. Use S-CAL calibrator to ensure accurate instrument measurements. Refer to the package insert for detailed information before use.

The differential and reticulocyte measurement devices are set for optimum performance at the factory.

1.7 REAGENTS

Coulter recommends these reagents or their equivalents. All stated performance characteristics in this manual are based on the use of the GEN•S System with these reagents. Refer to the container's label for detailed information before using the reagent.

Diluent

ISOTON® III diluent is an isotonic electrolyte solution that:

- Dilutes the whole-blood samples.
- Stabilizes cell membranes for accurate counting and sizing.
- Conducts aperture current.
- Rinses instrument components between analyses.
- Carries and focuses the sample stream in the flow cell to direct the blood cells through the aperture.

Since cell size (volume) is measured, the effect of diluent on osmosis or other phenomena must be tightly controlled. The diluent must not contain particles and must not support growth of bacteria or molds.

CBC Lytic Reagent

LYSE S® III Diff lytic reagent:

- Rapidly lyses erythrocytes (RBCs), freeing hemoglobin (Hgb) and reducing the size of cellular debris to a level that does not interfere with leukocyte (WBC) count.
- Causes a substantial conversion of the Hgb to a stable cyanide-containing pigment, the absorbance of which is directly proportional to the Hgb concentration over the clinical range.

SCATTER PAK Reagent System

The COULTER SCATTER PAK reagent system contains Erythrolyse II (PAK LYSE) and StabiLyse (PAK PRESERVE).

Erythrolyse II (PAK LYSE), Diff Lytic Reagent

Erythrolyse II erythrocyte lytic reagent:

- Dilutes the blood samples.
- Rapidly lyses erythrocytes (RBCs).
- Reduces cellular debris to an insignificant level.

StabiLyse (PAK PRESERVE), Diff Preservative

StabiLyse leukocyte preservative:

- Maintains leukocytes (WBCs) in their near-natural state.
- Allows the leukocytes to be differentiated into their subpopulations through the volume, conductivity and light-scatter measurements.

RETIC PAK Reagent System

The COULTER RETIC PAK contains Reagent A and Reagent B.

Reagent A, Retic Stain

Reticulocyte staining solution is a specially formulated, New Methylene Blue (NMB) dye that stains the reticulum.

Reagent B, Retic Clearing Solution

Reticulocyte clearing solution is a clearing reagent that removes hemoglobin from the erythrocytes (RBCs) without removing the precipitated dye-RNA complex, keeping the cell and its membranes intact.

Cleaning Agent

COULTER CLENZ® cleaning agent cleans and rinses the internal surfaces of the instrument components. Daily use prevents protein buildup and eliminates the need for routine aperture bleaching.

1.8 MATERIAL SAFETY DATA SHEETS (MSDS)

To obtain an MSDS for Coulter reagents used on the GEN•S System:

In the USA, write to:

Coulter Corporation
Attn: MSDS Requests
P.O. Box 169015
Miami, FL 33116-9015

Outside the USA, contact your Coulter Representative.

2.1 GENERAL

CAUTION Possible system damage can occur if you uncrate the instrument, install it or set it up. Keep the instrument in its packaging until your Coulter Representative uncrates it for installation and setup.

Your instrument is tested before it is shipped from the factory. International symbols and special handling instructions printed on the shipping cartons tell the carrier how to handle this electronic instrument.

Carefully inspect all cartons when they arrive. If you see any sign of mishandling or damage, file a claim with the carrier immediately. If the shipment is separately insured, file a claim with the insurance company.

2.2 SPECIAL REQUIREMENTS: HARDWARE

Install and operate this instrument in a conventional clinical laboratory environment. Since the individual units are all interrelated, you must determine the system location and layout before your Coulter Representative arrives to install the instrument. Consider the following special requirements.

Space and Accessibility

In addition to the space required for the individual components, consider:

- Comfortable working height.
- Access to perform service procedures. Allow at least 46 cm (18 in.) for the rear doors plus sufficient room for work space. Units can be moved to obtain additional work space.

Electrical Input

CAUTION Introduction of electrical interference causing the instrument to lock up or reset frequently can occur if you do not plug the primary power cables directly into an electrical outlet. Overheating, melting and burning of the power lines can occur if you use an extension cord with the primary power cables. Plug the primary power cables directly into an electrical outlet. Place the instrument close enough to an electrical outlet that an extension cord is not needed.

This instrument requires:

- An independent protected circuit
- A three-wire outlet furnishing the applicable line voltage, single-phase input power
- A ground path capable of carrying the full current of the circuit (confirmed thirdwire earth ground)
- That the 3-m (10-ft) primary power cord on the rear of the Power Supply be plugged directly into the electrical outlet. Do not use an extension cord.

Current-carrying capacity of 20 A is recommended, although the actual power consumption is only 1650 W.

Building outlets must be properly grounded and transients protected.

Ambient Temperature and Humidity

Operate the system in a room with a temperature of 15.5° to 32°C (60° to 90°F) and humidity up to 95% without condensation.

If the average room ambient temperature changes more than 5.5°C (10°F) from the calibrating temperature, verify calibration and recalibrate if necessary to ensure conformance to specifications.

Air Conditioning

In air-conditioned environments, an additional 5,500 Btu is required to compensate for the heat the system generates.

Ventilation

All ventilation fans must be at least 25 cm (10 in.) away from walls or obstructions that could interfere with the flow of air.

Drainage

CAUTION Incomplete waste chamber drainage and eventual waste chamber overflow into the vacuum system can occur if the waste line is too long. Contact your Coulter Representative if you need to increase the length of the waste line supplied with the instrument.

WARNING Biohazardous contamination could occur from contact with the waste container and its associated tubing if not handled with care. Avoid skin contact. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and acceptable laboratory procedures.

The maximum waste line length is 3.7 m (12 ft). The waste drain tubing (rear panel of the Diluter) supplied with the system can be connected to either:

- An open drain, suitable for biohazardous waste, less than 76 cm (30 in.) above the floor
- A waste container with a minimum capacity of 20 L (5 gal.).

When using an open drain instead of a waste container:

1. Insert the level sensing tube into the drain.
2. Be sure that the end of the tube is not below the normal level of the drain.
3. Mechanically secure the waste tube into the drain so the tube cannot accidentally come out of the drain. This prevents spillage.

Be sure to dispose of waste in accordance with environmental protection regulations.

2.3 INTERUNIT CONNECTIONS

Power and Signal Cables

Figure 2.2 shows the interunit connections of the power and signal cables that are supplied with the instrument. Your Coulter Representative makes these connections when installing the instrument.

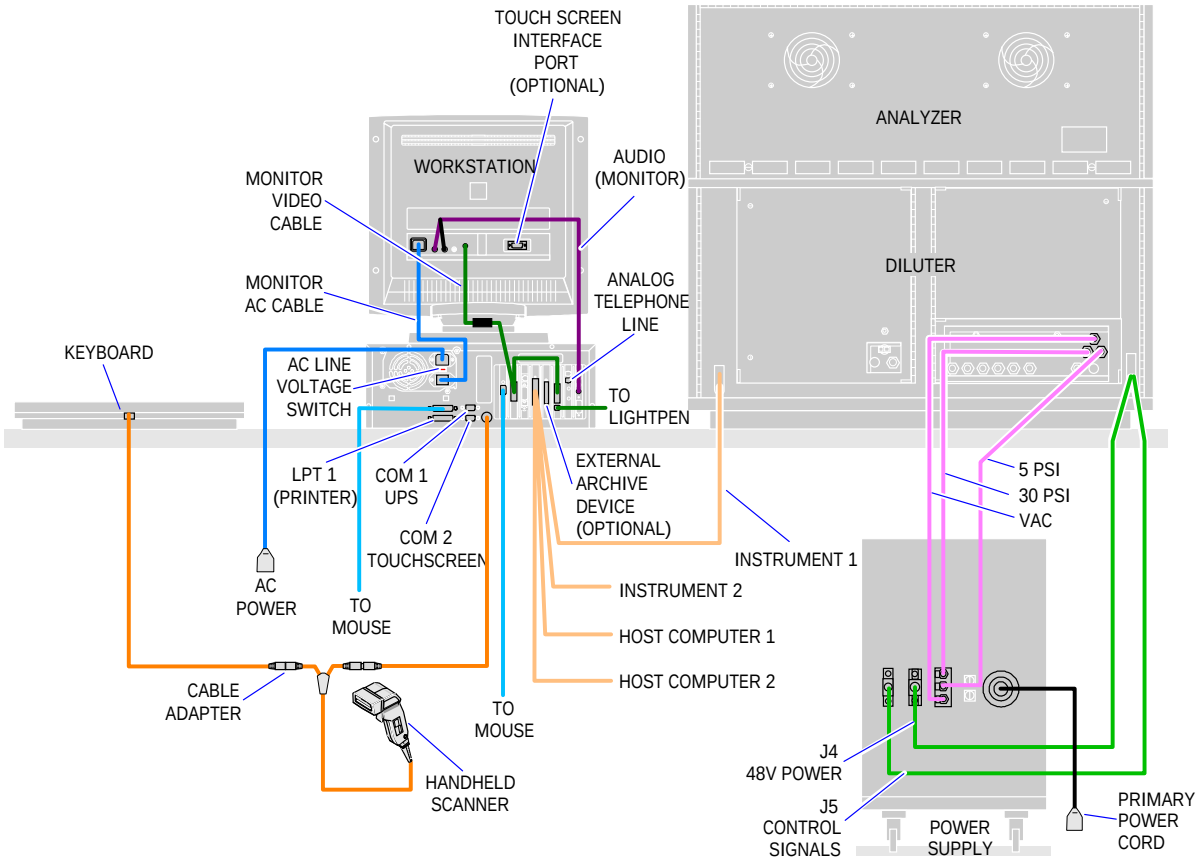

Figure 2.1 Interunit Power and Signal Cable Connections

Pneumatic/Hydraulic Tubing Connections

CAUTION Possible reagent siphoning effect and priming problems can occur if a reagent container is placed above the level of the Analyzer. Do not place reagent containers above the level of the Analyzer.

Figure 2.3 shows the tubing connections between the Diluter and the:

- Reagent containers
- Waste container
- Power Supply pressure and vacuum supplies.

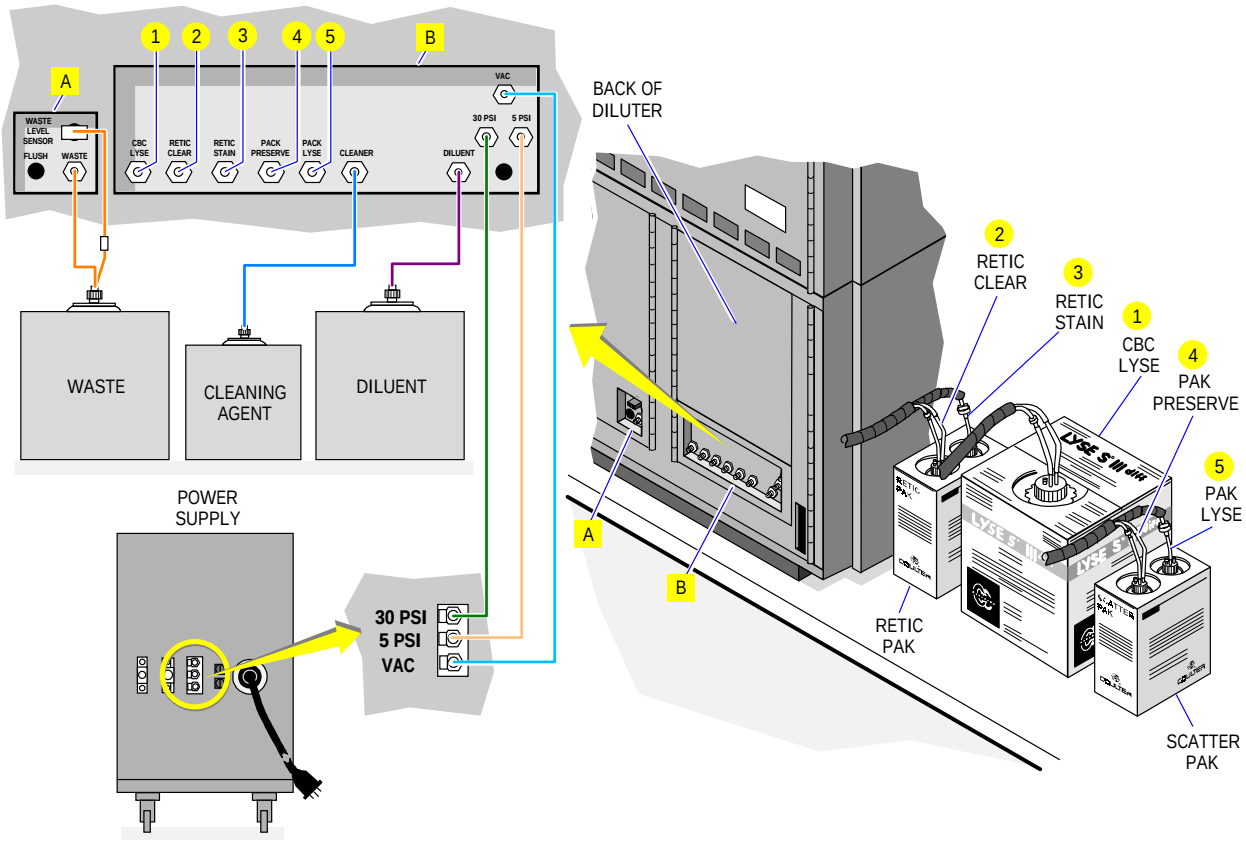

Figure 2.2 Pneumatic/Hydraulic Connections

3.1 COULTER METHOD

CBC Analysis

The Coulter method counts and sizes cells by detecting and measuring changes in electrical resistance when a particle (such as a cell) in a conductive liquid goes through a small aperture. See Figure 3.1.

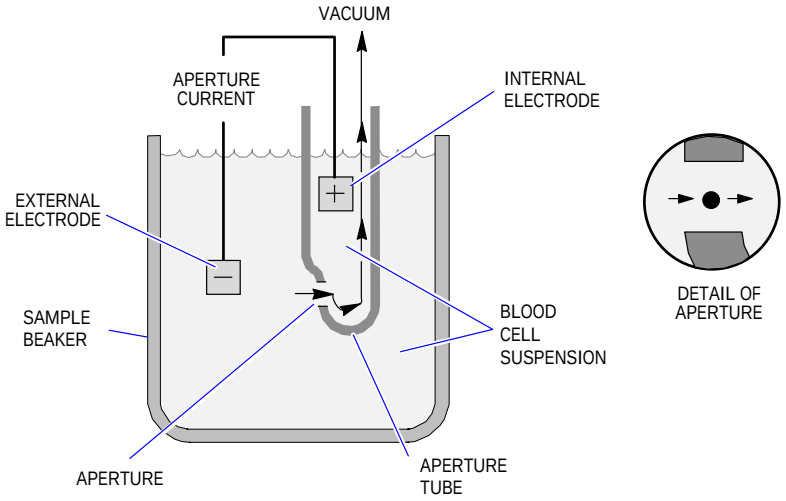

Figure 3.1 Coulter Method of Counting and Sizing

Each cell suspended in a conductive liquid (diluent) acts as an insulator. As each cell goes through the aperture, it momentarily increases the resistance of the electrical path between two submerged electrodes, one located on each side of the aperture. This causes an electrical pulse that can be counted and sized.

While the number of pulses indicates particle count, the size of the electrical pulse is proportional to the cell volume.[35 36 37 38]

Differential Analysis

WBC differential analysis and classification occurs in the flow cell, where:

- Low-frequency current measures volume,
- High-frequency current senses cellular internal content through measuring changes in conductivity,
- Light from the laser bouncing off the individual WBC cells characterizes cellular surface, shape and reflectivity.

Effect of Reagents

The conductive diluent must affect cells minimally, if at all.

Both lytic reagents must destroy erythrocytes without significantly affecting leukocytes. They must work rapidly to satisfy the speed with which the system works.

The leukocyte preservative must

- Provide clear separation of the white blood cell populations, and
- Preserve leukocytes in their near-natural state for accurate cytometric measurement.

Reticulocyte Analysis

A supravital dye, New Methylene Blue, is incubated with whole-blood samples. The dye precipitates the basophilic RNA network found in reticulocytes. Hemoglobin and unbound stain are removed by adding a clearing reagent, leaving clear spherical mature RBCs and darkly stained reticulocytes.

Stained reticulocytes are differentiated from mature red cells and other cell populations by light scatter, direct current measurements, and opacity characteristics.

3.2 AUTOMATIC ASPIRATION MODE

The system automatically transports, mixes, aspirates and processes specimens.

Loading Specimens

1. The operator places specimen tubes, which can be identified by bar-code labels, into cassettes. Each cassette and the tube positions in the cassette are identified by bar-code labels.
2. You can load up to 12 standard cassettes with 144 samples into the loading bay at one time. Figure 3.2 shows the loading bay filled with cassettes.

Transporting Cassettes

The system transports each cassette from the loading bay to the sampling station.

1. The right lift platform (Figure 3.2) rises beneath the stacked cassettes in the loading bay.
2. The bottom cassette is deposited on the platform.
3. The platform lowers the cassette to the level of the rocker bed.

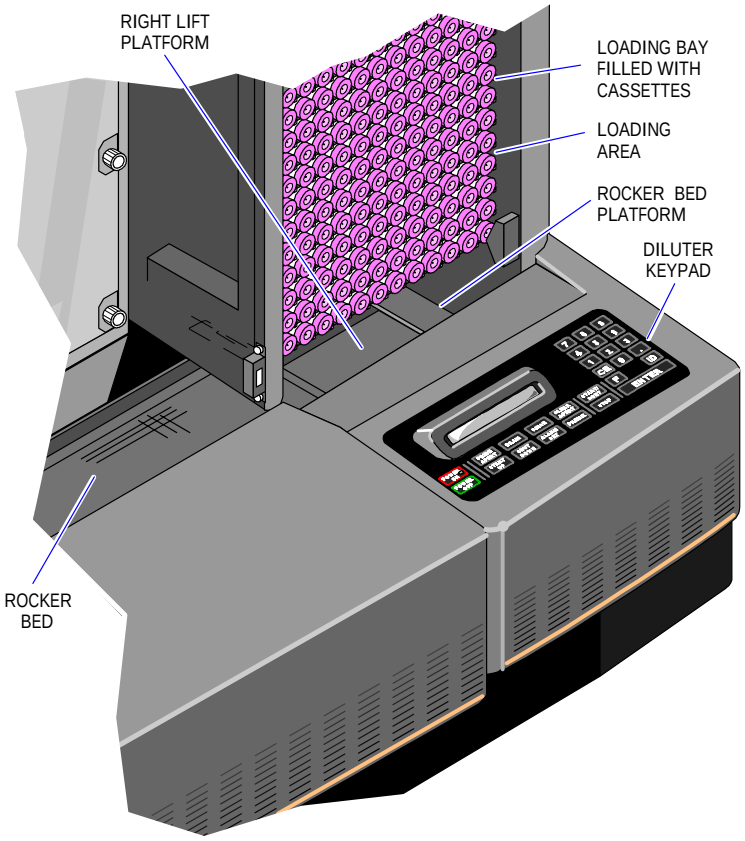

Figure 3.2 Transport System

4. The cassette moves onto the rocker bed where it rocks back and forth, mixing the specimens.
5. The cassette moves toward the sensing station until it reaches the tube sensor.
6. When the first tube is sensed, the stripper plate locks onto the tube.
7. After at least 14 rocks from the time the cassette was loaded, the rocker bed locks in a 45-degree forward position.
8. At the sampling station, the tube is locked in position.
9. The tube ram pushes the tube out from the cassette, causing the needle to pierce the tube stopper.
10. The bar-code reader scans the cassette and tube labels on both its forward and return passes; an audible indicator can be enabled to indicate each correctly-read bar code.

- If the two bar-code scans are identical, the bed continues to rock, and the cassette moves forward until the next available tube reaches the sampling station.
  If the bar-code reader detects a discrepancy between the forward and return readings, it makes an additional pass.
- If the bar-code reader cannot read the cassette bar-code label, the Diluter stops, posts a message on the Analyzer, Diluter and Workstation displays, backwashes the system, then returns to the Ready state.

- If Cass/Pos is the Positive Identifier, and the bar-code reader cannot read the tube bar-code label, dashes (-----) appear in the Sample ID field on the Workstation with the sample results.

11. After the last tube in the cassette is aspirated, the cassette continues along the rocker bed and is deposited onto the unloading bay platform. The left platform lifts the cassette into the exit bay, where up to 12 cassettes can be stacked.

Aspiration

At the sampling station, after the cap is pierced:

1. A pump draws a maximum of 300 mL of sample through the needle and through the Blood Sampling Valve (BSV).
2. The blood detectors monitor the passage of sample through the BSV and aspiration lines.
3. The needle is withdrawn and the sample tube is reseated in the cassette.

Delivery

CBC

After the sample is aspirated:

- The center section of the BSV rotates and segments the sample into two separate volumes.
- Beginning a few seconds before the delivery of the dilutions to the appropriate baths, 5 psi of pressure is sent to the WBC bath. This pressure allows drainage of any residual liquid in the WBC bath, thus preventing carryover.
- The pressure continues during delivery and forms bubbles that mix each cell suspension before sensing begins.
- At the beginning of the delivery, any residual rinse in the Hgb cuvette drains into the waste chamber and the waste chamber drains.
- Diluent from the diluent dispensers drives the separated volumes of sample from the BSV to the baths.
- One volume of sample, 1.6 µL, is delivered with 10 mL of diluent to the RBC bath. This dilution is used for RBC/Plt counting and MCV/Plt sizing.
- The other volume, 28 µL, is delivered with 6 µL of diluent to the WBC bath. This dilution is used to count WBC and develop Hgb.
- During delivery to the WBC bath, 1 mL of lytic reagent is added to the dilution to lyse the red cells and convert Hgb.
- At the same time the lytic reagent is dispensed, the Hgb-blank pump transfers 5 mL of diluent into the Hgb cuvette for the Hgb blank reading.
- The final dilution in the WBC bath is 1 part whole blood in a total volume of 251 parts. The final dilution in the RBC bath is 1 part whole blood in a total volume of 6250 parts.
- The vent section of the piercing needle is rinsed, then dried by high vacuum.
- The center section of the BSV returns to the aspirate position.

Differential (Diff) and Retic

At the same time as the segmented parts of the sample are being delivered to the baths, the Diff and Retic segmenting modules segment additional 34 µL samples of the blood for analysis.

- For the WBC differential, the sample and approximately 0.506 mL of heated Diff lytic reagent are delivered to the mixing chamber, which agitates to mix them thoroughly. During the mixing process, approximately 0.2 mL of Diff preservative enters the mixing chamber to preserve the leukocyte populations, and the instrument initiates the sheath stream of diluent in the triple-transducer flow cell.
- For the Retic analysis, the sample and approximately 166 µL of Retic stain are delivered to the Stain chamber, where they are mixed, heated and incubated for 31 seconds.

  A 2-µL segment of the stain/blood mixture and 2.00 mL of heated or chilled Retic clearing solution are delivered to the Retic chamber, where they are mixed and incubated for 25 seconds.

  The sample line between the Retic chamber and the flow cell is primed with the stain/blood/clearing solution before cell counting begins. After the sample line is primed, the flow cell is cleaned and primed with diluent, and the sheath stream of diluent begins.

For both the WBC differential and the Retic analysis, the instrument injects the sample into the center of the sheath stream and activates the flow cell aperture current. The laminar flow guides the sample through the center of the flow cell aperture; the sheath stream on the exit side of the flow cell aperture prevents the sample's cells from re-entering the aperture.

CBC Sensing System

Vacuum, equal to 6 in. of mercury, draws a precise volume of suspension from each bath through the three apertures. At the same time, sweep flow is drawn behind the RBC apertures to prevent cells from re-entering the sensing zone.

When the vacuum starts to draw the suspension, current is supplied to the electrode. The electrical path allows sensing of the number and volume of each cell pulled through the apertures.

While the sample in each bath is sensed, the photometer reads the Hgb-blank and the Analyzer retains this reference voltage.

CBC Analysis in the Baths

The RBC and Plt data collected at the RBC bath, and the WBC and Hgb data collected at the WBC bath and Hgb cuvette are sent to the Analyzer. There the data is:

- Counted
- Coincidence-corrected
- Scaled for calibration and dilution
- Voted on

The system derives the MCV and RDW parameters from the RBC histogram; it derives the Plt and MPV parameters from the Plt histogram. These parameters and histograms are sent to the Workstation along with the WBC count.

The WBC bath drains into the Hgb cuvette. The liquid in the cuvette is read photometrically and the Hgb concentration is calculated by comparing this reading with the Hgb-blank reference voltage retained in the Analyzer. This result is sent to the Workstation at the end of the cycle. The Workstation displays the test results and histograms. Results may be printed or transmitted.

Differential and Retic Multiparameter Sensing System

For the WBC differential and for the Retic analysis, the multiparameter sensing system produces the three measurement signals. Figure 3.3 shows the Triple Transducer Module and its protective housing as it resides in the Diluter.

WARNING The laser beam can cause damage to your eyes and to the instrument. Do not attempt to remove the laser from the Diluter module. If removal is required, it must be done only by a Coulter Representative.

Tamper-proof screws secure the protective housing; they can only be removed with a special tool.

The laser is a helium-neon laser that complies with the United States' performance standard for laser products, Title 21 Code of Federal Regulations 1040.10 and 1040.11. Figure 3.4 shows the laser module without its protective housing to display the flow cell and label locations.

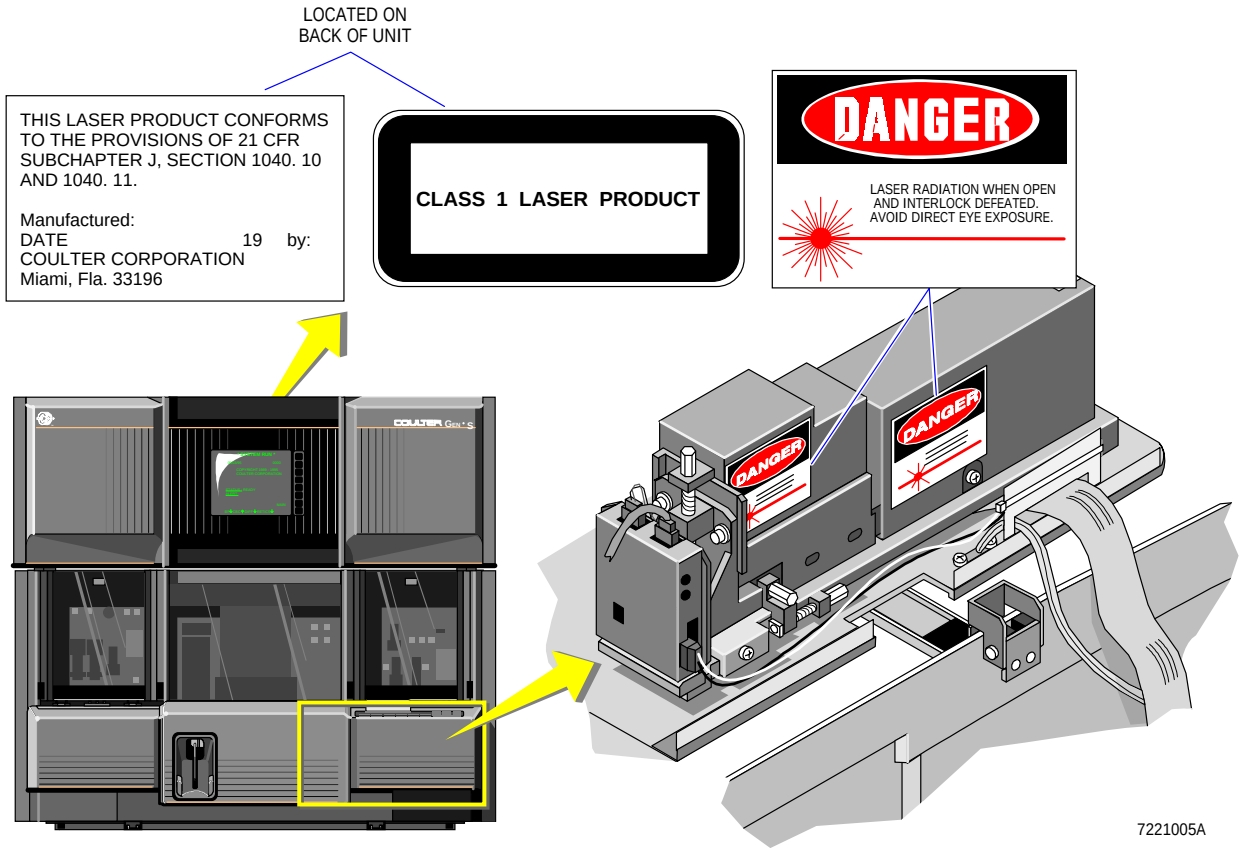

Figure 3.3 Triple Transducer Module with Protective Housing

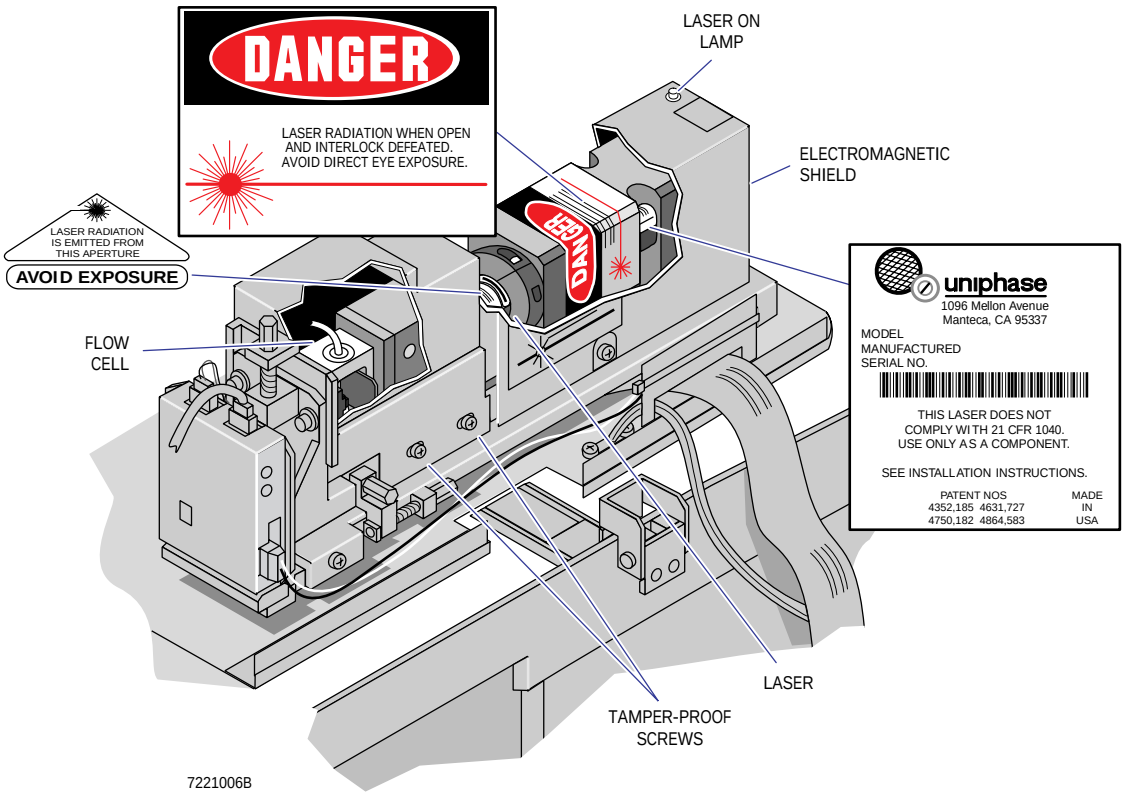

Figure 3.4 Triple Transducer Module with Protective Housing Cut Away

Note: As installed in the Triple Transducer Module (TTM) safety fixture, the laser presents no radiation hazard to users and complies with 21 CFR 1040.

WBC Differential Analysis

The GEN•S System makes three measurements (volume, conductivity, and scatter) as each cell passes through the flow cell.

The low-frequency impedance measurement defines cell volume. The high-frequency conductivity measurement indicates the internal conductivity. The light-scatter measurement indicates the structure and shape.

Three raw analog signals are sent to the Analyzer for amplification and signal processing. The Analyzer sends this raw data to the Workstation for computation and DataPlot generation of the five differential parameters. The Analyzer sends the CBC results to the Workstation. All results are displayed at the same time.

Reticulocyte Analysis

Reticulocyte samples are run in one of the three RETIC modes. The modes, which are set at the Analyzer, are:

RETIC
CBC/RETIC
CBC/DIFF/RETIC

The GEN•S uses the Triple Transducer Module to measure these parameters:

- Reticulocyte percent (RET%) - the number of reticulocytes per 100 RBCs, directly measured and reported as a percentage of RBCs.
- Reticulocyte number (RET#) - the absolute number of reticulocytes, calculated from RET% and RBC number. Expressed and reported as 10^6 cells/µL or 10^9 cells/L (US units).

Backwash and Rinse

The Diluter performs backwash of aspiration pathways and rinses its components.

Approximately 0.5 mL of Erythrolyse II erythrocyte lytic reagent is delivered to the mixing chamber to remove residual material from the previous cycle.

10 mL of diluent rinse for the WBC bath comes from the RBC diluent dispenser, and 6 mL of diluent rinse for the RBC bath comes from the WBC diluent dispenser. The WBC bath needs a larger rinse volume to

- Remove RBC cell stroma after lysing
- Remove remaining lytic reagent
- Rinse above the 7 mL fill line
- Rinse the hemoglobin cuvette.

3.3 MANUAL ASPIRATION MODE.

IMPORTANT Clots in the specimen can cause misleading results. The blood detectors are not active in the Manual mode. Be sure to inspect the specimen for clots, and use good laboratory practices to verify results.

The Manual mode of operation is like the Automatic mode except:

- Before you run the sample, you enter the sample identification number by performing any of the following--
  - Scanning the bar-code label on the tube
  - Entering the ID number on the Diluter keypad
  - Entering the ID number in the bar-code field on the GEN•S Workstation from its keyboard.
- You use an open vial and introduce the sample at the aspirator tip.
- You begin the cycle by either
  - Obstructing the optical sensor's beam
  - Pressing the panel behind the tip.
- The system aspirates a maximum of 200 µL of sample.
- The blood detectors are not active in the Manual mode.

3.4 COUNTING AND SIZING

Red and White Blood Cell Counting

The RBC and WBC baths each have three discrete apertures that function as independent systems. The six aperture currents are individually adjusted during calibration. When the Aperture Current/Signal Generator (API-SIG GEN) card applies current to the apertures, there is a delay. During this delay, the system conditions the electronics to perform the counting and sizing of the sample.

Regulated vacuum draws a precise volume of sample dilution through the apertures. At each aperture, the system gathers pulses for 4 seconds. The RED/WHITE PRE-AMP cards amplify these pulses and the Analyzer screen displays them.

The system sends these pulses to the RED/WHITE PROCESSOR card. Here

- Pulses from the RBC bath representing cells 36 fL and greater (volume calibration referenced to latex particles in ISOTON III diluent) are classified as red cells.
- Pulses from the WBC bath representing cells greater than 35 fL (volume calibration referenced to latex particles in ISOTON III diluent) are classified as white cells.

The system sends the RBC and WBC counts to the Analyzer computer for coincidence correction and voting. The Analyzer sends the final counts to the Workstation, which displays them, then to the Printer, if requested, for hard-copy reporting.

Coincidence Correction

Occasionally, more than one cell passes through the aperture at the same time. When cells coincide, the Analyzer counts only one pulse. As the frequency of coincidence is proportional to the actual count, the system automatically corrects results for coincidence.

Voting

To prevent data errors due to statistical outliers or obstructions that may block an aperture, the Analyzer votes on the data from all of the apertures, and rejects any questionable data. For the WBC count, RBC count, MCV, RDW, Plt count, and MPV, the Analyzer computer compares the data from the three apertures. It verifies that at least two apertures have produced data within an established statistical range of each other.

If the data from one aperture is outside the established statistical range, the computer votes out the data and histograms from that aperture. The computer derives the affected parameter by averaging the data from the two remaining apertures.

The data from at least two of the three apertures must be within an established statistical range of each other, or the system totally votes out the parameter and histograms. When a parameter totally votes out, the system does not give any results for the affected parameter or for any parameters that are derived from it. See your Online Help System or Operator's Guide for codes and messages that appear in these circumstances.

Pulse Editing

When cells pass through the aperture near the edge or at an angle rather than at the center, they create atypical pulses. The RED/WHITE PROCESSOR card edits RBC and WBC pulses to exclude these atypical pulses from analysis because they distort the true size of the cell. This

prevents the atypical pulses from influencing size measurement. Each of the six apertures has an editor.

Sweep Flow

The sweep flow is a steady stream of diluent that flows behind the RBC aperture during the sensing period. This prevents cells from re-entering the sensing zone and being counted as platelets. See Figure 3.5.

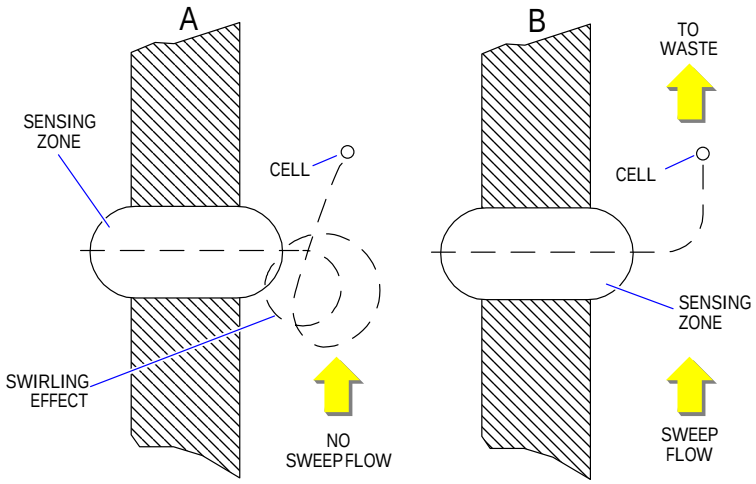

Figure 3.5 Sweep Flow

RBC Size Distribution

After editing, the RED/WHITE PROCESSOR converts the three sets of both the RBC and WBC pulses. It converts each pulse to a number that corresponds to the size of the cell. The Analyzer Microcontroller card (AMC) reads this data and generates histograms. The digital information from each aperture is stored according to volume in 256-channel, size-distribution histograms.

To ensure that the size-distribution curve accurately reflects the true cell population, the system extends RBC sensing for up to eight additional 2-second sensing periods whenever the RBC data accumulations are below a predetermined value. The RBC size distribution curve reflects the total data accumulated in all of the sensing periods.

After the sensing periods are completed, the system sends these histograms through the Communication Interface (COMM INTFC) card to the Workstation for display.

Plt Count and Size Distribution

In the PLATELET PROCESSOR card, pulses representing cells from 2 to 20 fL are classified as platelets.

To ensure that the Plt count and size-distribution curve accurately reflect the cell population, if the Plt data accumulation is below a predetermined level, the system extends Plt sensing for up to eight additional 2-second sensing periods. When sensing time is extended, the Plt count is divided by the number of sensing periods; the Plt size-distribution curve reflects the

total of data accumulated in all of the sensing periods. The system digitizes the Plt pulses. The AMC card reads the digital information and stores it in 64-channel, size-distribution histograms.

After the sensing periods are completed, the system sends these histograms through the COMM INTFC card to the Workstation for display.

Plt Fitting Process

The AMC card verifies that the Plt count per aperture is greater than 20 x 10^3 cells/µL, then it smoothes the histogram from each aperture, and finds in each of the smoothed curves a maximum point and two minimum points. Using a least-squares fit method for a log-normal curve, it fits a curve to the portion of the histogram between the two minimum points.

The computer verifies that each of the fitted curves

- Is positive
- Has a mode between 3 and 15 fL
- Has a PDW less than 20. NOTE: This is an approximate value since comparison is made based on raw data prior to multiplication by the calibration factor.

The fitted curves have a range of 0 to 70 fL.

The computer votes on the Plt count, MPV, and PDW derived from the three fitted curves. If any of these criteria are not met, a no-fit condition exists. A NON POS, MODE OUT, or PDW OUT message appears on the Analyzer CRT in the SYSTEM RUN mode.

If a no-fit occurs, the AMC smoothes the histogram from each aperture, and locates in certain areas of each of the smoothed curves a maximum point and two minimum points. The computer then derives the Plt count for each aperture from the portion of the histograms between the minimum points. Then the computer votes on the Plt count, MPV, and PDW derived from the raw data.

Retic Parameters

The system makes three measurements as each cell passes through the flow-cell aperture:

- The low-frequency impedance measurement, which defines the cell's volume
- The high-frequency impedance measurement, which indicates the cell's internal conductivity
- The light-scatter measurement, which indicates the cell's structure and shape.

3.5 MEASUREMENT OF HEMOGLOBIN CONCENTRATION

After the WBC count, the lysed WBC dilution drains into the hemoglobin cuvette for Hgb measurement.

A beam of white light from an incandescent lamp goes through the cuvette and then through an optical filter that has a center transmission wavelength of 525 nm. Light passing through the filter falls on a photocell. The photocurrent thus generated is proportional to the transmittance of the contents of the cuvette at the chosen wavelength. It is sent to the COMM

INTFC card where it is digitized. The digital information is sent to the Analyzer computer, then to the Workstation.

A significant refinement of the COULTER systems is the introduction of a reagent blank into the cuvette during each operating cycle. After the percent transmittance is converted to absorbance, the reagent-blank signal level provides a reference to which the sample signal is compared.

3.6 DATAPLOT DEVELOPMENT

The Workstation performs a series of operations on the stored digital raw values received from the flow cell to identify memberships (subpopulations) and calculate the frequency of cells within each membership group. It also produces the DataPlot displays for visual representation of the WBC Diff and Reticulocyte/RBC membership and density.

In the GEN•S System, the COULTER AccuGate™ algorithm uses adaptive contouring methods designed for finding optimal separation between overlapping clusters of data. The AccuGate algorithm provides a statistical analysis tool that discovers the overlapping populations using nonlinear separation techniques. The newly developed adaptive gating techniques use multidimensional data to distinguish the presence of even the faintest subpopulation. The AccuGate algorithm can adapt to unusual population shifts and overlaps. It can define highly irregular separation, and signal the need for further analysis. It can then make a subsequent analysis of the identified regions and correct deficiencies in separation.

In the DataPlots, different colors represent different memberships (types of cells). Shades of colors represent density (concentration): dark colors for low density, bright colors for high density.

DIFF:	Lymphocytes	Blue
	Neutrophils	Purple
	Eosinophils	Orange
	Monocytes	Green
	Basophils	White
	Non-white debris	Red
RETIC:	RBCs	Red
	Reticulocytes	Blue
Platelets		Green
WBCs		Purple

Two-Dimensional (2D) DataPlots

The 2D WBC Diff DataPlot shows the five memberships: lymphocytes (LY), monocytes (MO), neutrophils (NE), eosinophils (EO) and basophils (BA), plus the non-white cell populations. Cell volume (VOL), determined by the low-frequency impedance measurement, is plotted on the Y-axis; rotated light scatter (RLS) is plotted on the X-axis.

The Reticulocyte DataPlot shows mature red cells and Reticulocytes. Cell volume is plotted on the Y-axis, and linear light scatter (LLS) is plotted on the X-axis.

Three-Dimensional (3D) DataPlots

The 3D DataPlot view classifies by density, light scatter and opacity. The axes are color coded.

On the WBC differential DataPlot the axes are:

Volume = green
RLS (rotated light scatter) = red
OP (opacity) = blue

On the Retic DataPlot the axes are:

Volume = green
LLS (linear light scatter) = red
OP (opacity) = blue

3.7 PARAMETERS AND THEIR DERIVATION

Mathematical expressions in this section are in U.S. units of measurement. Parameter units can be changed to other International System of Units (SI) through Setup on the GEN•S Workstation.

White Blood Cell (WBC) Count

WBC is the number of leukocytes measured directly, multiplied by the calibration factor. This number is expressed as

$$WBC = n \times 10^3 \text{ cells} / \mu L$$

Red Blood Cell (RBC)

RBC is the number of erythrocytes measured directly, multiplied by the calibration factor. This number is expressed as

$$RBC = n \times 10^6 \text{ cells} / \mu L$$

Hemoglobin (Hgb) Concentration

The transmittance of light (525 nm wavelength) through the lysed WBC solution in the hemoglobin cuvette is compared to the transmittance of the same light through a reagent blank. The system converts this ratio to an Hgb value in g/dL using a calibration factor.

Weight (mass) of hemoglobin determined from the degree of absorbance found through photocurrent transmittance is:

$$HGB\ (g / dL) = \text{Constant} \times \log_{10} \frac{\text{Reference \%T}}{\text{Reference \%T}}$$

Mean Corpuscular Volume (MCV)

MCV is the average volume of individual erythrocytes derived from the RBC histogram. The system multiplies the number of RBCs in each channel by the size of the RBCs in that channel. The products of each channel between 36 fL and 360 fL are added. This sum is divided by the total number of RBCs between 36 fL and 360 fL. The analyzer then multiplies

by a calibration constant and expresses MCV in femtoliters.

Hematocrit (Hct)

Hct is the relative volume of packed erythrocytes to whole blood, computed by the formula:

HCT (%)= (RBC x MCV) / 10

Mean Corpuscular Hemoglobin (MCH)

MCH is the weight of hemoglobin in the average erythrocyte, computed by the formula:

MCH (pg) = (HGB/RBC) x 10

Mean Corpuscular Hemoglobin Concentration (MCHC)

MCHC is the average weight of hemoglobin in a measured dilution, computed by the formula:

MCHC (g/dL) = (HGB/HCT) x 100

Red Distribution Width (RDW)

RDW is the size distribution spread of the erythrocyte population derived from the RBC histogram. It is the coefficient of variation (CV) expressed in percent of the RBC size distribution.

Platelet (Plt) Count

Plt is the number of thrombocytes derived from the Plt histogram and multiplied by a calibration factor. This number is expressed as:

$$PLT = n \times 10^3 \text{cells} / \mu L$$

Mean Platelet Volume (MPV)

MPV is the average volume of individual platelets derived from the Plt histogram. It represents the mean volume of the Plt population under the fitted Plt curve multiplied by a calibration factor. This number is expressed in femtoliters.

Differential (Diff)

Diff Percentages (DIFF%)

The percentages of leukocytes from each category are derived from the DataPlot.

$$NE\% = \frac{\text{no. of cells inside NE area}}{\text{no. of cells inside NE + LY + MO + EO + BA}} \times 100$$

$$LY\% = \frac{\text{no. of cells inside LY area}}{\text{no. of cells inside NE + LY + MO + EO + BA}} \times 100$$

$$MO\% = \frac{\text{no. of cells inside MO area}}{\text{no. of cells inside NE + LY + MO + EO + BA}} \times 100$$

$$EO\% = \frac{\text{no. of cells inside EO area}}{\text{no. of cells inside NE + LY + MO + EO + BA}} \times 100$$

$$BA\% = \frac{\text{no. of cells inside BA area}}{\text{no. of cells inside NE + LY + MO + EO + BA}} \times 100$$

Diff Absolute Numbers (DIFF#)

The absolute numbers of leukocytes in each category are computed from the WBC count and differential percentage parameters.

$$NE\ (10^3\ \text{cells} / \mu L) = \frac{NE\%}{100} \times \text{WBC count}$$

$$LY\ (10^3\ \text{cells} / \mu L) = \frac{LY\%}{100} \times \text{WBC count}$$

$$MO\ (10^3\ \text{cells} / \mu L) = \frac{MO\%}{100} \times \text{WBC count}$$

$$EO\ (10^3\ \text{cells} / \mu L) = \frac{EO\%}{100} \times \text{WBC count}$$

$$BA\ (10^3\ \text{cells} / \mu L) = \frac{BA\%}{100} \times \text{WBC count}$$

Reticulocyte (Retic) Parameters

Retic Percent (RET%)

Number of reticulocytes per 100 RBCs. This parameter is directly measured and reported as %, a percentage of RBCs.

Retic Absolute Number (RET#)

Absolute number of reticulocytes computed from the reticulocyte percent (RET%) multiplied by the RBC count.

$$RET\# = \frac{RET\% \text{ x RBC Count}}{100}$$

Summary of Parameter Derivations

Parameters are either:

- Measured directly.
- Derived from the RBC or Plt histogram.
- Computed.

Measured Directly

Parameter	Method
RBC	Coulter Principle
WBC	Coulter Principle
Hgb	Photometric Measurement
DIFF% parameters	VCS Technology
RET%	VCS Technology

Derived From RBC or Plt Histogram

Parameter	Derived From
MCV	RBC Histogram
RDW	RBC Histogram
Plt	Plt Histogram
MPV	Plt Histogram

Note: The histograms are developed using the Coulter Principle. Therefore, indirectly, these parameters are derived from the Coulter Principle as well.

Computed

Hct
MCH
MCHC
DIFF# parameters
RET#

3.8 $\overline{x}_B$ ANALYSIS

Studies (Bull 1974, Koepke 1981) indicate that the red cell indices (MCV, MCH, and MCHC) of patient populations are stable over time.[39] [40] This stability characteristic of the indices is the basis of a quality-control technique called $\overline{x}_B$ Analysis. In a manually implemented system, population means (target values) are established by analyzing as large a sample as possible, at least 250, but ideally 1,000 blood samples. (The $\overline{x}_B$ Analysis used in the Workstation does all the calculating automatically.) Once the target values have been established, the $\overline{x}_B$ Analysis can be applied using quite small batches from the patient population. A 20-patient sample batch is a typical size, and can be used in the GEN•S Workstation.

Here is the $\overline{x}_B$ formula.

$$X(B,i) = X(B,i-1) + SGN\left\{\sum_{j=1}^{N} SGN[X(j,i) - X(B,i-1)] \times \sqrt{|X(j,i) - X(B,i-1)|}\right\} \times F$$

$$F = \frac{\left\{\sum_{j=1}^{N} SGN\left[X(j,i) - X(B,i-1) \times \sqrt{|X(j,i) - (B,i-1)|}\right]\right\}^2}{N^2}$$

Where:

X(B,i)	= ith XB value
X(B, i-1)	= (i-1)th XB value
X(j,i)	= the jth X value in the ith batch
SGN	= the arithmetic sign of number in parentheses
N	= number of samples in the batch
x	= symbol used to represent multiplication

The formula is easily implemented with a computer. Its function is to enable reliable estimates of the values for these parameters to be made for a population from small samples of that population. It is superior to the traditional moving average because it reacts quickly to changes. Small batch sizes allow for more frequent, therefore tighter quality control. The formula both trims the data by giving less weight to outliers, and smoothes it by incorporating information from the previous patient batch in the analysis of the current batch. As each sample is processed, the mean of the previous set of samples is subtracted from each of the red cell indices. The square root of this deviation (difference between the means) is stored. After 20 samples have been processed, the sum of the square roots is divided by 20. The result is squared to recover the mean (average) deviation. The individual deviations carry a positive or negative sign, so then it can be added to or subtracted from the corresponding previous means. The resulting new mean is then used for the succeeding batch of 20 samples.

The hematology system is considered "in control" when the batch means are within established limits of the target values. Using the $\bar{x}_B$ Analysis, the direction and amount of change due to the instrument, the reagent, flagged samples or sample handling can be detected. Because of the characteristic appearance of the graphs of the XB results, it is also often possible to identify changes.

The GEN•S Workstation calculates and displays the percent difference between each batch mean and its corresponding preset target value. The percent difference is derived as follows:

MCV

$$\text{percent diff} = \left(\frac{\text{MCV Batch Mean}}{\text{MCV Target Value}} - 1 \right) \times 100$$

MCH

$$\text{percent diff} = \left(\frac{\text{MCH Batch Mean}}{\text{MCH Target Value}} - 1 \right) \times 100$$

MCHC

$$\text{percent diff} = \left(\frac{\text{MCHC Batch Mean}}{\text{MCHC Target Value}} - 1 \right) \times 100$$

Adjusting Initial $\bar{x}_B$ Target Values

The recommended target values for initial entry are:

MCV 89.5
MCH 30.5
MCHC 34.0

As samples are run and laboratory values established, the recommended target values can be adjusted to fit your laboratory's population. After 20 $\overline{x}_B$ batches have been analyzed, calculate the mean and CV% for each of the XB indices. The mean values should not differ from the target values by more than 3%, and the CV should be less than 1.5%. If the CVs are less than 1.5% and the means are less than 3% different from the target values, use the calculated means as new target values.

If the CVs are greater than 1.5%, or the mean values are greater than 3% different from the recommended target values, there may be an instrument or population problem. In this case, repeat this procedure using the next 20 $\overline{x}_B$ batches. If the indices themselves are stable in a hospital population, then any deviation from the Target Values and Action Limits may point to an instrument or reagent problem. These problems would involve the parameters directly measured by the instrument and used to calculate the red cell indices. Table 3.1 lists the directly measured parameters that would be involved with out-of-limits $\overline{x}_B$ batch values for each of the red cell indices.

If the $\overline{x}_B$ indices are still out-of-limits, you should investigate the instrument and reagent systems associated with the directly-measured parameter(s) as indicated by Table 3.1 and call your Coulter Service Representative.

Table 3.1 Effect of Directly Measured Parameters om thje Red Cell Indiceses

Index	**Directly-Measured Parameter**					
	MCV		**RBC**		**HGB**	
	Increased	Decreased	Increased	Decreased	Increased	Decreased
MCV	HIGH	LOW	NORMAL	NORMAL	NORMAL	NORMAL
MCH	NORMAL	NORMAL	LOW	HIGH	HIGH	LOW
MCHC	LOW	HIGH	LOW	HIGH	HIGH	LOW

See the Glossary for terms used with the $\overline{x}_B$ Analysis.

4.1 PHYSICAL SPECIFICATIONS

Dimensions

Unit	Height*	Width*	Depth*	Weight
Analyzer	35.6 cm (14 in.)	99.1 cm (39 in.)	38.1 cm (15 in.)	49.9 k (110 lb)
Diluter	50.8 cm (20 in.)	99.1 cm (39 in.)	55.9 cm (22 in.)	54.4 k (120 lb)
Power Supply	63.5 cm (25 in.)	38.1 cm (15 in.)	66.0 cm (26 in.)	56.7 k (125 lb)

* ±5.1 cm (2 in.)

Power

Input

Power Supply:	90 - 264 Vac, 47 - 63 Hz
Workstation:	90-135 Vac, 47-63 Hz or 180-265 Vac, 47-63 Hz

Consumption

1650 W (5500 BTU/h) maximum

Installation Category: per IEC 1010-1, Category II

Temperature

Ambient operating range for patient samples: 15.5 to 32°C (60 to 90°F)

Humidity

0 to 95% without condensation

Sample Stability

CBC/Diff Parameters

- Stored at room temperature, up to 24 hours after collection
- Stored between 2 and 8°C (35.6 and 46.4°F), up to 48 hours after collection

Reticulocyte Parameters

Stored between 2 and 8°C (35.6 and 46.4°F), up to 72 hours after collection

Sample Storage

Room temperature (23.9°C, 75°F) up to 24 hours

Sample Type

Anticoagulated human whole blood

Recommended Anticoagulant

K_2EDTA or K_3EDTA

Sampling Modes

Aspiration

Automatic cap-piercing, whole blood
Manual, open vial, whole blood

Test/Cycle

CBC
CBC/DIFF
CBC/RETIC
CBC/DIFF/RETIC
RETIC

Throughput, Automatic Mode

Typical throughput performance is described as "average" for samples exhibiting parameter levels within the normal range, and "maximum" for samples with elevated parameter levels. Approximate throughput performance data, not including sample preparation, is:

	Average	Maximum
CBC	105	120
CBC/Diff	105	110
CBC/Diff/Retic	50	55

Throughput requirements are based on the sample criteria in Table 4.1.

Table 4.1 Throughput Sample Criteria

Parameter	RETIC modes	CBC	CBC/DIFF
WBC	N/A	> 7.0 x 10^3/µL	> 7.0 x 10^3/µL
RBC	> 5.0 x 10^6/µL	> 5.0 x 10^6/µL	> 5.0 x 10^6/µL
Plt	N/A	> 300.0 x 10^3/µL	> 300.0 x 10^3/µL

Sample Volume Aspirated

Automatic, cap-piercing mode: maximum 300 µL
Manual, open-vial mode: maximum 200 µL

Waste

20-liter waste container

Pneumatic Supplies (Internally Regulated)

Pressure = 60 psi (pounds per square inch)
Vacuum = 22 in. Hg (inches of mercury) minimum at sea level

Calibration Stability

Electronic measurement system: < 1% per month

Variation with temperature: If ambient room temperature changes by less than 5.5þC (10þF) from the calibrating temperature, and the temperature is within the temperature

specifications, then the GEN•S System does not require calibration. Under these conditions, the expected variation in calibration factors is:

WBC	<1.25%	MCV	<1.18%
RBC	<0.70%	Plt	<2.70%
Hgb	<0.78%	MPV	<5.00%

Gen•s Workstation Storage

Patient results: 5,000 sets including all DataPlots and histograms.

4.2 PERFORMANCE SPECIFICATIONS

The GEN•S System consists of three subsystems, designated as "CBC" (Complete Blood Count), "WBC Differential" and "Retics." The CBC subsystem is based on the established Coulter principles of automated cell counting. The WBC differential subsystem is based on the Coulter principles of leukocyte differential counting as embodied in the COULTER VCS. The Retics subsystem is based on the Coulter volume, conductivity and light scatter technology.

Performance specifications stated apply only to an instrument that has been properly maintained as indicated in the COULTER GEN•S System documentation, using the recommended reagents.

If the average room temperature should change more than 5.5°C (10°F) from the calibrating temperature, verify calibration and recalibrate if necessary to ensure conformance to specifications.

Precision

Within-Run Precision

Within-run Precision is based on at least 31 determinations of the same sample. See Table 4.2.

Table 4.2 Within-Run Precision (n = 31)

Parameter	@ Approximate Level	Limit
WBC	9 to 11 x 10^3 cells/µL	≤1.7% CV
RBC	4.5 to 5.5 x 10^6 cells/µL	≤0.8% CV
Hgb	14 to 16 g/dL	≤0.8% CV
MCV	80 to 90 fL	≤0.8% CV
RDW	12 to 14%	≤2.2% CV
Plt	280 to 320 x 10^3 cells/µL	≤3.3% CV
Plt	90 to 110 x 10^3 cells/µL	≤6.6% CV
Plt	10.0 to 15.0 x 10^3 cells/µL	≤14.0% CV
MPV	8 to 10 fL	≤2.2% CV
NE%	50 to 60%	2SD ≤3.0
LY%	25 to 35%	2SD ≤3.0
MO%	5 to 10%	2SD ≤2.0

Table 4.2 Within-Run Precision (n = 31)

Parameter	@ Approximate Level	Limit
EO%	2 to 5%	2SD ≤1.0
BA%	0.5 to 1.5%	2SD ≤1.0
RET%	0.00 to 0.49%	1SD ≤0.23 or 16.5% CV
RET%	0.50 to 1.49%	1SD ≤0.23 or 14.5% CV
RET%	1.50 to 4.00%	1SD ≤0.68 or 11.0% CV
RET%	4.01 to 15.00%	1SD ≤0.68 or 5.5% CV

Accuracy

Accuracy Qualification

Accuracy is tested on a minimum of 150 non-flagged, morphological normal samples for CBC and Diff, and 50 non-flagged samples for Retics. Distributional abnormal samples should be included. NCCLS H20-A criteria should be used in the sample selection and manual differential examination.

Accuracy, CBC

For the CBC parameters, the GEN•S System can be adjusted within the resolution of the readout to agree with a predetermined reference value at any point in the operating range. Table 4.3 lists the specifications for the mean difference and mean percent difference.

Table 4.3 Accuracy, CBC

Parameter	Mean Difference	Mean Percent Difference
WBC	±0.2	3.0%
RBC	±0.05	2.0%
Hgb	±0.2	3.0%
MCV	Not Applicable	2.0%
RDW	±0.5	5.0%
Plt	±10	7.0%
MPV	Not Applicable	5.0%

Accuracy, WBC Differential

Accuracy of the WBC differential should be determined by comparison against the manual differential reference method (NCCLS H20-A [n = 400]).

When the GEN•S System is compared to NCCLS H20-A, using non-flagged, morphological normal samples, expect results within tolerance limits listed in Table 4.4.

Table 4.4 Accuracy Tolerance Limits, WBC Differential

Cell Type	Mean Difference %
Lymphocyte	±3.0
Monocyte	±3.0
Neutrophil	±2.0
Eosinophil	±1.0
Basophil	±1.0

Accuracy, Reticulocyte

Reticulocyte parameter (RET%) accuracy can be determined against either or both of two comparator methods. Accuracy can be tested against a clinical flow cytometer following the guidelines of NCCLS H44-P. Accuracy can be also tested against the manual method using NCCLS H16-P. See Table 4.5.

Table 4.5 Accuracy, Reticulocyte

Parameter/Population	Mean Difference	SD of Difference
RET% Range 0.00 to 15.00% <30% have a RET% >4.00	±1.00	≤1.50
RET% Range 0.00 to 30.00% <50% have a RET% >4.00 <10% have a RET% >20.00	±1.50	≤3.00

Linearity

When tested using a stable material having no interfering substances, the GEN•S System value should be equal to the expected value within the limits given in Table 4.6. To minimize the effects of imprecision, take multiple readings at each dilution point. Subtract the background count from the values obtained.

Table 4.6 Linearity Limits

Parameter	Linearity Range	Limits (mean difference or % difference, whichever is greater)
WBC x 10^3 cells/µL	0.00 to 100.0 100.1 to 140.0	±0.2 or 3.0% 12%
RBC x 10^6 cells/µL	0.00 to 8.00	±0.05 or 2.0%
Hgb g/dL	0.0 to 25.0	±0.2 or 3.0%
Plt x 10^3 cells/µL	0 to 1500	±10 or 7.0%

Background

Background counts for CBC parameters are performed during the Startup cycle. The background limits are:

WBC	≤0.20
RBC	≤0.01
Hgb	≤0.15
Plt	≤3.00
Diff	≤100 events
Retic	≤600 events

Carryover

High-to-Low Carryover on the GEN•S System should meet these limits:

WBC	≤2.0%	DIFF	≤200 events
RBC	≤1.0%	RETIC	≤600 events
Hgb	≤2.0%		
Plt	≤2.0%		

Operating and Reportable Ranges

The operating ranges reflect the range of values over which the instrument displays, prints and transmits results. Values that are between the linear range and the operating range, and values outside the reportable range, are displayed, printed and transmitted with an over linear range flag (+). Values that are above the operating range are inhibited, and the value is replaced by pluses (+++++). The reportable range identifies the values where the instrument is accurate, and reflects the range studied in accuracy testing. See Table 4.7.

Table 4.7 Operating and Reportable Ranges

Parameter	Operating Range	Reportable Range
WBC	0.00 to 500.00 x 10^3 cells/µL	0.00 to 140.00 x 10^3 cells/µL
RBC	0.00 to 20.00 x 10^6 cells/µL	0.00 to 8.00 x 10^6 cells/µL
Hgb	0.0 to 99.9 g/dL	0.0 to 25.0 g/dL
Hct	0.0 to 99.9%	N/A
MCV	0.0 to 300.00 fL	0.0 to 150.0 fL
MCH	0.0 to 99.9 pg	N/A
MCHC	0.0 to 99.9 g/dL	N/A
RDW	0.0 to 99.9%	N/A
Plt	0.00 to 2500 x 10^3 cells/µL	0.00 to 1500 x 10^3 cells/µL
Pct	0.0 to 9.999%	N/A
MPV	0.0 to 99.9 fL	N/A
PDW	0.0 to 99.9%	N/A
NE%, LY%, MO%, EO%, BA%	0 to 100%	0 to 100%
NE#, LY#, MO#, EO#, BA#	0.00 to 500.00 x 10^3 cells/µL	0.00 to 100.00 x 10^3 cells/µL

Table 4.7 Operating and Reportable Ranges

Parameter	Operating Range	Reportable Range
RET%	0.00 to 100%	0.00 to 30.0%
RET#	0.00 to 999.9 x 10^6 cells/µL	0.0000 to 0.7500 x 10^6 cells/µL

Mode-to-Mode Comparison

Automatic (closed vial) and Manual (open vial) mode-to-mode differences of the means of 10 hematologically "normal" blood specimens, measured in triplicate, or 50 samples from accuracy testing should be less than or equal to the following:

WBC ± 0.4 x 10^3 cells/µL or 5%, whichever is greater
RBC ± 0.2 x 10^6 cells/µL or 2%, whichever is greater
Hgb ± 0.3 g/dL or 2%, whichever is greater
Plt ± 20 x 10^3 cells/µL or 7%, whichever is greater

In addition, 95% of the individual differences should be within the stated limits.

4.3 PERFORMANCE CHARACTERISTICS

Precision

Precision was measured through replicate testing, in the Automatic mode, of stabilized blood control material (three levels of COULTER 5C Cell Control, and Retic-C Cell Control) and normal whole-blood specimens.

CBC Parameters, 5C® Cell Control

Table 4.8 shows the CBC results for 31 replicate determinations of 5C Normal cell control, 5C Abnormal I cell control and 5C Abnormal II cell control.

Table 4.8 CBC Precision, 5C Cell Control

Parameter	5C Normal Cell Control		5C Abnormal I Cell Control		5C Abnormal II Cell Control	
	Mean	CV%	Mean	CV%	Mean	CV%
WBC	8.82	0.73	19.47	0.73	3.46	1.20
RBC	5.521	0.579	4.111	0.566	1.812	0.532
Hgb	16.84	0.30	13.13	0.24	5.14	0.33
MCV	89.97	0.33	90.00	0.37	84.60	0.18
RDW	14.70	1.15	14.95	1.31	15.65	1.27
Plt	231.99	1.37	436.73	1.85	75.97	1.63
MPV	10.57	0.55	10.54	0.74	9.37	0.67

WBC Differential Parameters, 5C Cell Control

Table 4.9 shows the WBC Differential results for 31 replicate determinations of 5C Normal cell control, 5C Abnormal I cell control and 5C Abnormal II cell control.

Table 4.9 WBC Differential Precision, 5C Cell Control

Parameter	5C Normal Cell Control		5C Abnormal I Cell Control		5C Abnormal II Cell Control	
	Mean	**2SD**	**Mean**	**2SD**	**Mean**	**2SD**
NE%	54.04	1.09	65.26	1.13	42.94	2.04
LY%	29.28	1.40	13.70	0.65	46.42	2.20
MO%	8.23	0.86	14.87	0.80	5.95	0.55
EO%	8.32	0.73	6.09	0.57	4.41	0.59
BA%	0.13	0.11	0.07	0.07	0.28	0.26

Reticulocytes, Retic-C Cell Control

Table 4.10 shows Retic results for 31 replicate determinations of Retic-C Cell Control.

Table 4.10 Reticulocytes Precision, Retic-C Cell Control

	Level I	Level II	Level III
Mean	0.982	2.708	9.802
SD	0.086	0.114	0.267
CV%	8.807	4.200	2.723

CBC Parameters, Whole Blood

Table 4.11 shows the CBC results for 31 replicate determinations of whole blood in K_3EDTA.

Table 4.11 CBC Precision, Whole Blood

Parameter	Mean	CV%
WBC	6.87	1.13
RBC	4.391	0.597
Hgb	13.68	0.40
MCV	89.28	0.62
RDW	11.71	1.62
Plt	235.02	2.05
MPV	10.14	1.02

WBC Differential, Whole Blood

Table 4.12 shows the WBC Differential results for 31 replicate determinations of whole blood in K_3EDTA, Automatic Mode.

Table 4.12 WBC Differential Precision, Whole Blood

Parameter	Mean	2 SD
NE%	51.09	1.22
LY%	37.07	1.09
MO%	8.23	0.78
EO%	3.25	0.40
BA%	0.35	0.12

Reticulocyte Precision, Whole Blood

The RET% results for 31 replicate determinations of whole blood in K_3EDTA, Automatic Mode are:

Mean = 1.064
1 SD = 0.068
CV% = 6.386

Accuracy

Accuracy for the CBC parameters was characterized by comparing results obtained from a GEN•S System with values given by the STKS Analyzer with Reticulocyte Analysis. The five-part differential results were compared to values given by the reference method (NCCLS H20-A). Reticulocyte results were compared to values given by the reference method (NCCLS H16-P) and the COULTER EPICS XL-MCL Flow Cytometry System using Thiazole Orange. The GEN•S and STKS instruments were calibrated with S-CAL calibrator.

Accuracy of the CBC Parameters

In this study, accuracy for the CBC parameters was defined as the agreement between the STKS with Reticulocyte Analysis instrument and the GEN•S System using clinical specimens with values covering the expected range of performance. Estimates of agreement were made by pair-difference analysis. The magnitude of the Mean Difference or Mean Percent Difference expresses accuracy; see Table 4.13.

Table 4.13 CBC Accuracy Analysis: Compared Samples, Auto Mode

Parameter	Units	N	Population Minimum	Population Maximum	Mean Difference	SD	Mean % Difference
WBC	x 10^3 cells/µL	256	0.25	80.12	0.12	0.26	1.93
RBC	x 10^6 cells/µL	273	1.217	8.360	0.012	0.042	0.310
Hgb	g/dL	270	4.86	24.63	0.02	0.10	0.26
MCV	fL	273	67.4	116.6	-0.17	0.67	-0.18
RDW	%	264	11.53	32.24	0.22	0.30	1.48
Plt	x 10^3 cells/µL	237	23.9	1562.4	-3.26	15.51	-0.57
MPV	fL	239	6.18	11.03	0.11	0.26	1.47

Accuracy of the Differential Parameters

Accuracy for the Differential parameters was defined as the agreement between the GEN•S System and NCCLS H20-A Reference Methodology for the five-part differential parameters. Estimates of agreement were made by pair-difference analysis. The magnitude of the Mean Difference expresses accuracy; see Table 4.14..

Table 4.14 Diff Accuracy Analysis: Compared Samples, Auto Mode

Parameter	Units	N	Population Minimum	Population Maximum	Mean Difference	SD
NE	%	189	7.25	82.75	-0.72	3.20
LY	%	189	9.25	90.50	-1.06	3.22
MO	%	189	1.25	18.25	1.80	1.74
EO	%	189	0.00	13.50	0.15	1.02
BA	%	189	0.00	4.75	-0.16	0.53

Accuracy of Reticulocytes

Accuracy for Reticulocyte parameters was defined as the agreement between the GEN•S System with the comparator Flow Cytometry instrument and NCCLS H16-P manual reference methodology. Estimates of agreement were made by pair-difference analysis. The magnitude of the Mean Difference and SD of the difference expresses accuracy. See Table 4.15.

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Table 4.15 Retic Accuracy Analysis: Compared Samples, Auto Mode

Parameter	Units	N	Population Minimum	Population Maximum	Mean Difference	SD
RET*	%	262	0.00	18.50	-0.33	0.83
RET**	%	261	0.00	13.40	-0.51	0.61

* NCCLS

** Flow Cytometer

Clinical Sensitivity

Criteria as described by the NCCLS Reference Method were used to determine the effectiveness of the GEN•S System flagging in identifying morphologically normal and abnormal specimens. In addition to H20-A, the following criteria were also used to determine a reference method positive:

- Proportional cell count of >10% for variant lymphocytes
- Other abnormal cells (such as Plasma cells, Hairy cells, and so forth) at cell counts equivalent to characteristics used to examine blast cell types.
  - Absolute cell count ≥0.1 x 10^3 cells/µL
  - Proportional Cell Count >2%

See Table 4.16

.

Table 4.16 Clinical Sensitivity of Instrument Flagging

	Percent		Absolute Number	
Condition	**Number of Cases**	**Criteria %**	**Number of Cases**	**Criteria x 10^3 cells/µL**
Lymphocytosis	13	> 50	15	≥ 3.5
Lymphopenia	24	< 7	60	≥ 1.0
Variant Lymphocytes	16	> 10	22	≥ 0.7
Monocytosis	37	> 10	36	≥ 0.8
Immature Cells Including Blasts	52	> 2*	63	≥ 0.1*
Eosinophilia	15	> 7	16	≥ 0.5
Bands	50	> 6	30	≥ 0.9
Granulocytosis	11	> 80	21	≥ 9.0
Granulocytopenia	9	< 10	24	≤ # 1.5
Nucleated RBC	11	> 2	25	≥ 0.02

* The limit specified in NCCLS H20-A is that the combined total of immature cells, including blasts should be > 2%, or ≥0.1.

Flagged results from the GEN•S System were compared to the NCCLS guideline H20-A manual reference method.

True Negative (TN) False Negative (FN)
True Positive (TP) False Positive (FP)

Table 4.17 shows the clinical sensitivity for morphologic abnormals.

Table 4.17 Clinical Sensitivity for Morphologic Abnormals, Default Differential Flagging Preferences*

	Positive (Abnormal)		Negative (Normal)		Total	
	GEN•S System A	**GEN•S System B**	**GEN•S System A**	**GEN•S System B**	**GEN•S System A**	**GEN•S System B**
Reference Positive (Abnormal)	38 (TP)	38 (TP)	13 (FN)	13 (FN)	51	51
Reference Negative (Normal)	23 (FP)	28 (FP)	192 (TN)	186 (TN)	215	214
Total	61	66	205	199	266	265

*Instrument Positive selections = Blast, variant Lymph, NRBC, and Imm NE 2 at mid-level, Imm NE 1 ON (default).

Summary

	GEN•S System A	GEN•S System B	Calculation
Agreement (Efficiency)	86.47	84.53	[(TP+TN)/TOTAL] x 100
FP Ratio (NCCLS)	10.70	13.08	[FP/(FP+TN)] x 100
FN Ratio (NCCLS)	25.49	25.49	[FN/(FN+TP)] x 100
% FP (% of Total)	**8.65**	**10.57**	**[FP/Total Number] x 100**
% FN (% of Total)	**4.89**	**4.91**	**[FN/Total Number] x 100**
Prevalence: %Normal	215/280 (76.79%)	214/280 (76.43%)	[REF. NORM./TOTAL] x 100
Prevalence: % Abnormal	65/280 (23.21%)	66/280 (23.57%)**	[REF. ABN./TOTAL] x 100

**Includes non-reportable results (for example, flow cell clog, Verify Diff suspect flag).

Individual Flagging Performance

GEN•S Workstation Software Version 2A allows individual selection of the following flags at three levels (low, mid, high): Blast, Variant Lymph, NRBC, Imm NE 2. The display, printing, and transmission of Imm NE 1 can be enabled or disabled.

Individual flagging performance for GEN•S system A and B is shown below, based on reference positive criteria described in NCCLS H20-A. This data was obtained from a database of approximately 4,200 clinical specimens.

	Low	Mid	High
BLAST			
Agreement (Efficiency)	92.09	90.99	89.37
FP Ratio (NCCLS)	7.89	9.08	10.81
FN Ratio (NCCLS)	8.55	7.24	5.92
%FP (% of Total)	7.60	8.75	10.41
%FN (% of Total)	0.31	0.26	0.21
VARIANT LYMPH			
Agreement (Efficiency)	98.16	97.66	94.61
FP Ratio (NCCLS)	1.33	2.01	5.34
FN Ratio (NCCLS)	36.67	25.0	8.33
%FP (% of Total)	1.31	1.98	5.27
%FN (% of Total)	0.52	0.36	0.12
NRBC			
Agreement (Efficiency)	96.76	93.28	80.48
FP Ratio (NCCLS)	2.35	6.47	20.36
FN Ratio (NCCLS)	21.65	11.86	2.06
%FP (% of Total)	2.24	6.17	19.42
%FN (% of Total)	1.00	0.55	0.10
Imm NE 2			
Agreement (Efficiency)	91.66	90.23	88.47
FP Ratio (NCCLS)	5.99	7.98	10.32
FN Ratio (NCCLS)	31.52	27.39	23.51
%FP (% of Total)	5.43	7.24	9.37
%FN (% of Total)	2.91	2.53	2.17

Reference Ranges

A Normal Range study was conducted to assess the Reference Ranges for the GEN•S System. Whole-blood samples were collected from 240 donors (equal numbers of males and females).

The selection of donors was consistent with guidelines stated in NCCLS, C28-A. See Table 4.18.

Table 4.18 Normal Population Study

Parameter	Units	Gender	Mean	95% Confidence Low Limit	95% Confidence High Limit
WBC	x 10^3 cells/µL	M/F	6.11	3.58	11.07
RBC	x 10^6 cells/µL	F	4.241	3.691	4.877
RBC	x 10^6 cells/µL	M	4.829	4.270	5.493
Hgb	g/dL	F	12.82	11.35	14.35
Hgb	g/dL	M	14.56	12.92	16.12
Hct	Ratio	F	37.10	33.27	41.39
Hct	Ratio	M	42.08	37.65	46.48
MCV	fL	M/F	87.36	79.30	94.80
MCH	pg	M/F	30.23	26.80	33.16
MCHC	g/dL	M/F	34.56	33.51	35.54
RDW	%	M/F	13.16	11.99	15.14
Plt	x 10^3 cells/µL	M/F	242.16	165.40	352.90
MPV	fL	M/F	8.87	7.51	10.65
LY	%	M/F	30.10	16.75	43.43
MO	%	M/F	7.95	4.63	12.37
NE	%	M/F	58.15	43.18	71.52
EO	%	M/F	2.74	0.70	7.80
BA	%	M/F	0.59	0.22	1.21
NE	x 10^3 cells/µL	M/F	3.58	1.86	7.17
LY	x 10^3 cells/µL	M/F	1.81	1.10	2.74
MO	x 10^3 cells/µL	M/F	0.48	0.29	0.84
EO	x 10^3 cells/µL	M/F	0.17	0.04	0.49
BA	x 10^3 cells/µL	M/F	0.04	0.01	0.08
RET	%	M/F	0.93	0.26	1.60
RET	x 10^6 cells/µL	M/F	0.04	0.01	0.07

Carryover

Carryover was measured by analyzing three consecutive samples of normal whole blood (H_1, H_2, H_3) followed by three consecutive samples of ISOTON III diluent (L_1, L_2, L_3). This sequence was repeated ten times. Mean values for each directly measured parameter (WBC, RBC, Hgb, Plt) for each sample type (L_1, L_2, L_3 and H_1, H_2, H_3) were calculated. These Mean Values were then used in the following calculations:

High-to-Low Carryover (H/L%): $H/L\% = ((L_1 - L_3)/(H_3)) \times 100$

Instrument High-to-Low carryover for the Differential (Diff) and Reticulocyte (Retic) parameters is tested to a limit of 200 events for the Diff parameters and 600 events for the Retic parameter. See Table 4.19.

Table 4.19 Carryover

Parameter	High-to-Low Carryover	Unit of Measure
WBC	0.50	%
RBC	0.33	%
Hgb	0.44	%
Plt	0.42	%
Diff	36	Events
Retic	245	Events

Mode-to-Mode

Mode-to-mode testing included analysis of 50 normal, whole-blood specimens in both the Automatic (closed vial) and Manual (open vial) modes on the GEN•S System. The Mean Values for WBC, RBC, Hgb and Plt for each mode were calculated. The individual differences, the average expressed as a mean, and the mean percent difference for each of the four parameters were calculated; see Table 4.20.

Table 4.20 Automatic Mode vs. Manual Mode

Parameter	N	Automatic Mode Mean	Manual Mode Mean	Mean Difference	Mean % Difference
WBC $x10^3/\mu L$	50	6.57	6.65	0.07	1.14
RBC $x10^6/\mu L$	50	4.760	4.812	0.048	1.009
Hgb g/dL	50	14.07	14.11	0.04	0.28
Plt $x10^3/\mu L$	50	245.8	243.9	-1.9	-0.6

Known Interfering Substances

CBC

WBC	Certain unusual RBC abnormalities that resist lysing, NRBC, fragmented WBC, any unlysed particle greater than 35 fL, very large platelets.
RBC	Very high WBC count, high concentration of very large platelets, auto-agglutination.
Hgb	Very high WBC count, severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing.
MCV	Very high WBC count, high concentration of very large platelets, auto-agglutination.
RDW	Very high WBC count, high concentration of very large platelets, auto-agglutination.
Plt	Very small erythrocytes or leukocytes, or cell fragments may cause no-fit conditions in some cases. The GEN•S system provides accurate Plt counts in the presence of most hemolytic disorders. Chemotherapy may affect certain samples.
Hct, MCH, MCHC	Known interferences related to the parameter used for computation.

Differential

Interfering substances for the Diff parameters: High triglycerides may affect lysing.

Reticulocytes

Erythrocyte inclusions stained by New Methylene Blue, if sufficiently numerous within a sample, and some hemoglobinopathies (SS, SC) might affect the accuracy of the reticulocyte enumeration.41

4.4 BAR-CODE LABEL SPECIFICATIONS

Handheld Scanner

Information about configuring the handheld scanner is located elsewhere.

General

A bar code consists of black lines (bars) and white lines (spaces), which are called elements. There are narrow elements (NE) and wide elements (WE); their arrangement is determined by the code.

IMPORTANT Possible misidentified results. For accurate reading by the scanner, it is important that bar-code labels for specimen tubes adhere strictly to the specifications given in this section. Labels that meet these specifications are available from Coulter.

Optical Characteristics At 880 Nm ±10% And 633 Nm ±10%

- Print Contrast Signal (PCS): 80% min.
- Reflectivity of Media (RW): 80% min.
- Reflectivity of Ink (Rb): 16% max.
- No spots or voids; no ink smearing.
- Edge roughness is included in the bar and space tolerances.

Measurement method is according to American National Standards Institute's MH10-8M-1983.

Printing Method

Photographic, or thermal transfer.

Label Thickness

Maximum label thickness must be such that:

- The tube's outer diameter including the label is not greater than 13.3 mm.
- The label including adhesive = 0.006 ±0.003 in.

Ne/we Ratio

Must remain constant over code length.

Label Dimensions And Data

The dimensional and data specifications are illustrated in Figure 4.1. Table 4.21 explains the specifications called out in Figure 4.1

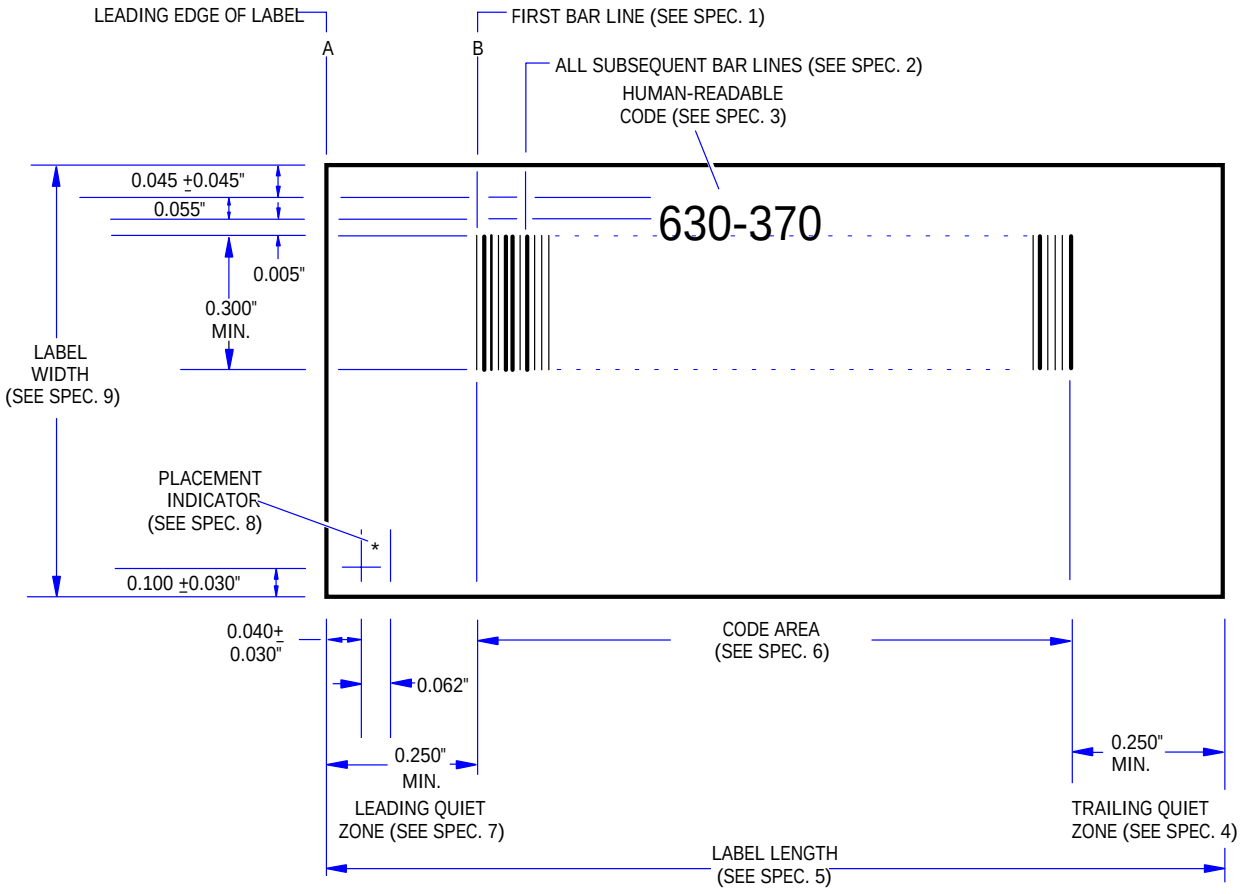

Figure 4.1 Bar-Code Label Specifications

Table 4.21 Bar-Code Label Specifications

Specification Called Out in Figure 4.1	Explanation
1	The first bar of the code (B) must be parallel to the label edge (A) within 0.002".
2	All subsequent bar lines must be parallel to (B) within 0.001".
3	The human-readable code (HRC) does not include the checksum; the dash in the HRC is not encoded in the bar code.
4	The trailing quiet zone must be 0.250" minimum.
5	The maximum label length is determined by the tube length. The scanner can accommodate labels up to 2.35". With HEMOGARD™ tubes, the maximum label length is 2.04".
6	The bar-code area contains the start character, data digits, checksum, and stop character.
7	The leading quiet zone must be 0.250" minimum.
8	The placement indicator shows you which end of the label goes next to the tube stopper. This is an optional feature, not a mandatory one.
9	The width of the label must leave at least a 1/8" window for viewing the contents of the tube. The maximum label width for a 10-mm diameter tube is 1.1". The minimum label width is 0.400".

Acceptable Bar Codes

Within the given specifications, the scanner automatically distinguishes the following bar codes.

Interleaved 2-of-5
Code 39 bar code
Codabar
NW7
Code 128/USS 128

The following table summarizes the code-related specifications.

Table 4.22 Code-Related Specifications

Code	Interleaved 2-of-5	Codabar	Code 39****	NW7	Code 128**** USS 128
Narrow element (NE) width	0.0105" ±0.001"	0.010"* Scaling Factor = 1.538*	0.010" ±0.001"	0.0105" ±0.001"	0.010" ±0.001"
Wide element/ narrow element ratio (WE/NE)	(2.2 to 3): 1	N/A	(2.21 to 3): 1	(2.2 to 3): 1	(2 to 4): 1**
Intercharacter gap	No	0.010" Min.	>=NE	0.010" Min.	No
Data digits	3 to 11	3 to 9	3 to 9 (3 to 8 with HEMOGARD tubes)	3 to 9	3 to 11 Checksum always printed***

* According to American National Standard for bar code specifications that yield 10 characters per inch at NE = 0.0065".

** Code 128 is character dependent. See AIM® Uniform Symbol Specification Rev. 1986 for additional required dimensional tolerances.

*** You must use and print a checksum character, and it must conform to the AIM USS 128 checksum generation procedure. Do not use these values:
Code set A - 0, 64 through 102
Code set B - 0, 95 through 102
Code set C - 100 through 102

**** Do not use leading or trailing spaces in the ID

Checksum Algorithm

Coulter strongly recommends the use of bar-code checksums to provide automatic checks for read accuracy.

IMPORTANT Use of bar codes is an extremely accurate and effective method of positive patient identification. Certain features, such as checksum digits, maximize accuracy in reading Codabar, Code 39 and Interleaved 2-of-5 labels. In one study, the use of checksum digits detected 97% of misread errors.

Use checksums to provide protection against occasional misread errors caused by problems such as damaged or misapplied labels. If you must use bar codes without checksums, Coulter recommends that you verify each bar-code reading to assure correct patient identification.

The algorithm for determining the checksum for each code is given below.

Interleaved 2-of-5

This code requires 3 to 11 data digits plus a checksum.

To determine the value of the checksum character:

1. Identify even- and odd-positioned characters in the message with the right-hand message character always defined as an even-positioned character.

2. Sum the numeric values of the odd-positioned characters.
3. Sum the numeric values of the even-positioned characters and multiply the total by 4. Sum the odd and even totals from steps 2 and 3.
4. Determine the smallest number which, when added to the sum in step 4, results in a multiple of 10.

   This number is the value of the checksum character.
5. Determine whether total number of characters (message plus checksum) is odd or even. If odd, add a leading nonsignificant zero to the message to produce an even number of characters as required by the symbology.

Example:

MESSAGE	1	2	5	6	7	8
PARITY	0	E	0	E	0	E

STEP 2: 1+5+7=13

STEP 3: (2+6+8)x3=48

STEP 4: 13+48=61

STEP 5: 61+9=70

Therefore, the checksum is 9, and the final decoded message is 01256789.

Codabar and NW7

These codes use three to nine data digits.

Note: Codabar and NW7 codes have the same character set and the same checksum algorithm. The difference between these two codes is that Codabar has 18 different bar and space dimensions, and NW7 has only NE and WE structure.

The value assigned to each of the characters is presented in the following table.

CHARACTER	VALUE	CHARACTER	VALUE
0	0	-	10
1	1	$	11
2	2	:	12
3	3	/	13
4	4	.	14
5	5	+	15
6	6	A	16
7	7	B	17
8	8	C	18
9	9	D	19

The checksum technique is:

- The character value of a message is obtained from the above table and added together.
- This sum is divided by 16, and the remainder corresponds to the value of the checksum character.

Examples:

1.

MESSAGE	2	3	4	7	1	3

VALUE	2	3	4	7	1	3

2+3+4+7+1+3 = 20
20 ÷ 16 = 1, REMAINDER 4

The value 4 corresponds to character 4; therefore, the checksum is 4 and the final decoded message is 2347134.

2.

MESSAGE	$	$	/	/	+	+	+	+
VALUE	11	11	13	13	15	15	15	15

11+11+13+13+15+15+15+15 = 108
108 ÷ 16 = 6, REMAINDER 12

The value 12 corresponds to character :, therefore, checksum is :, and the final decoded message is: $$//++++:

Japan Red Cross NW7 Decoding

This code uses three to nine data digits.

Japan Red Cross Hospitals use the following NW7 values:

CHARACTER	VALUE
0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

The checksum technique is:

- The data digit value that is the difference between 11 and the Mod 11 sum of the weighted values of the data digits is used as the check digit. The start and stop digits are not used as part of the checksum calculation.
- NW7 is made up of 1 start digit, 9 data digits and 1 stop digit.
- The checksum digit immediately precedes the stop digit.

WEIGHTED MODULUS 11:

DIGIT POSITION	12	11	10	9	8	7	6	5	4	3	2	1
(Right Justified)												
WEIGHT (1)	6	3	5	9	10	7	8	4	5	3	6	2
WEIGHT (2)	5	8	6	2	10	4	3	7	6	8	5	9

The first 9 digits from the right are used for the calculation of the check digit.

To determine the value of the checksum character:

1. Determine the Modulus 11 value corresponding to each character in the message.
2. Multiply each character in the message by the corresponding Mod 11 value.

3. Add the resulting values and divide by 11.
4. Subtract the remainder from 11.
5. Determine the character that corresponds to the result from step 4. This is the checksum character.

Examples:

1. MESSAGE 011529007

USE WEIGHT (1): 6 3 5 9 10 7 8 4 5 3 6 2

DIGIT POSITION	0	0	0	0	1	1	5	2	9	0		
(Right Justified)											**0**	**7**
WEIGHT (1)	6	3	5	9	10	7	8	4	5	3	**6**	**2**
Result	0	0	0	0	10	7	40	8	45	0	**0**	**14**

0 + 10 + 7 + 40 + 8 + 45 + 0 + 0 + 14 = 124
124 ÷ 11 = 11, REMAINDER 3
When the REMAINDER IS 0, 0 is the check digit.
11 - 3 = 8

The value 8 corresponds to character 8, therefore the checksum is 8 and the final decoded message is 0115290078

2. MESSAGE 023229006

USE WEIGHT (1): 6 3 5 9 10 7 8 4 5 3 6 2

DIGIT POSITION	0	0	0	0	2	3	2	2	9	0	0	6
(Right Justified)												
WEIGHT (1)	6	3	5	9	10	7	8	4	5	3	6	2
Result	0	0	0	0	20	21	16	8	45	0	0	12

0 + 20 + 21 + 16 + 8 + 45 + 0 + 0 + 12 = 122
122 ÷ 11 = 11, REMAINDER 1

When the REMAINDER is 1, the calculation must be repeated using weight (2): 5 8 6 2 10 4 3 7 6 8 5 9

DIGIT POSITION	0	0	0	0	2	3	2	2	9	0	0	6
(Right Justified)												
WEIGHT (2)	5	8	6	2	10	4	3	7	6	8	5	9
Result	0	0	0	0	20	21	6	14	54	0	0	54

0 + 20 + 12 + 6 + 14 + 54 + 0 + 0 + 54 = 160
160 ÷ 11 = 14, REMAINDER 6
When the REMAINDER is 0, 0 is the check digit.
11 - 6 = 5

The value 5 corresponds to character 5, therefore the checksum is 5 and the final decoded message is 0232290065.

Code 39® Bar Code

This code uses three to nine data digits.

The value assigned to each of the characters is:

CHARACTER	VALUE	CHARACTER	VALUE	CHARACTER	VALUE
0	0	F	15	U	30
1	1	G	16	V	31
2	2	H	17	W	32
3	3	I	18	X	33
4	4	J	19	Y	34
5	5	K	20	Z	35
6	6	L	21	-	36
7	7	M	22	.	37
8	8	N	23	SPACE	38
9	9	O	24	$	39
A	10	P	25	/	40
B	11	Q	26	+	41
C	12	R	27	%	42
D	13	S	28		
E	14	T	29		

The checksum technique is:

- The character values of the message are obtained from the above table and added together.
- This sum is divided by 43, and the remainder corresponds to the value of the checksum character.

Example:

CHARACTER	S	T	U	V	W	X	Y	F
VALUE	28	29	30	31	32	33	34	15

28+29+30+31+32+33+34+15 = 232
232 ÷ 43 = 5, REMAINDER 17; 17 = H = CHECKCHARACTER

The value 17 corresponds to character H; therefore, checksum is H, and the final decoded message is: STUVWXYFH.

Code 128

This code uses three to eleven data digits.

The checksum character immediately precedes the stop character. The checksum character used with Code 128 must conform to the AIM USS 128 checksum generation procedure. Do not use these values:

Code set A - 0, 64 through 102
Code set B - 0, 95 through 102
Code set C - 100 through 102

The checksum value (see the following table) is equal to the modula 103 sum of the value of the start character and the weighted values of the data/special characters. The weights are one for the first data/special character and continuing with two, three, four and so forth for the following data/special characters.

For example, a label contains a START character (Code C), Data (25), a Check character and a STOP character. The value of the Start character C is 105, and the data character for 25 is

25. The weight of the first data character is one, so the check character value is calculated as follows:

105 + (25 x 1) = 130

where 105 and 25 are the values and 1 is the weight.

The checksum is equal to 130 modula 103 (the remainder of 130 divided by 103):

130 ÷ 103 = 1, REMAINDER 27

Therefore the check character equals character value 27, which is ; in Code Set A.

For additional information on this procedure, refer to AIM USS-128 Rev. 1986, published by AIM, Inc., 1326 Freeport Road, Pittsburgh, PA 15238.

VALUE	CODE A	CODE B	CODE C
0	SP	SP	00
1	!	!	01
2	"	"	02
3	#	#	03
4	$	$	04
5	%	%	05
6	&	&	06
7	'	'	07
8	(	(	08
9	)	)	09
10	*	*	10
11	+	+	11
12	,	,	12
13	-	-	13
14	.	.	14
15	/	/	15
16	0	0	16
17	1	1	17
18	2	2	18
19	3	3	19
20	4	4	20
21	5	5	21
22	6	6	22
23	7	7	23
24	8	8	24
25	9	9	25
26	:	:	26
27	;	;	27
28	<	<	28
29	=	=	29
30	>	>	30
31	?	?	31
32	@	@	32
33	A	A	33
34	B	B	34
35	C	C	35
36	D	D	36
37	E	E	37
38	F	F	38
39	G	G	39
40	H	H	40
41	I	I	41
42	J	J	42
43	K	K	43
44	L	L	44
45	M	M	45

46	N	N	46
47	O	O	47
48	P	P	48
49	Q	Q	49
50	R	R	50
51	S	S	51
52	T	T	52
53	U	U	53
54	V	V	54
55	W	W	55
56	X	X	56
57	Y	Y	57
58	Z	Z	58
59	[	[	59
60	\	\	60
61	]	]	61
62			62
63	___	¯\	63
64	NUL		64
65	SOH	a	65
66	STX	b	66
67	ETX	c	67
68	EOT	d	68
69	ENQ	e	69
70	ACK	f	70
71	BEL	g	71
72	BS	h	72
73	HT	i	73
74	LF	j	74
75	VT	k	75
76	FF	l	76
77	CR	m	77
78	SO	n	78
79	SI	o	79
80	DLE	p	80
81	DC1	q	81
82	DC2	r	82
83	DC3	s	83
84	DC4	t	84
85	NAK	u	85
86	SYN	v	86
87	ETB	w	87
88	CAN	x	88
89	EM	y	89
90	SUB	z	90
91	ESC	{	91
92	FS	|	92
93	GS	}	93
94	RS	~	94
95	US	DEL	95
96	FNC 3	FNC 3	96
97	FNC 2	FNC 2	97
98	SHIFT	SHIFT	98
99	CODE C	CODE C	99
100	CODE B	FNC 4	CODE B
101	FNC 4	CODE A	CODE A
102	FNC 1	FNC 1	FNC 1
103	START (CODE A)		
104	START (CODE B)		
105	START (CODE C)		

5.1 LASER SAFETY.

WARNING Possible harm to operator. Do not use any controls, make any adjustments, or perform any procedures other than those specified herein. To do so may result in hazardous radiation exposure.Use of bar codes is an extremely accurate and effective method of positive patient identification. Certain features, such as checksum digits, maximize accuracy in reading Codabar, Code 39 and Interleaved 2-of-5 labels. In one study, the use of checksum digits detected 97% of misread errors.

The Triple Transducer Module contains a laser. The laser is a unique light source that exhibits characteristics different from conventional light sources. The safe use of the laser depends upon familiarity with the instrument and the properties of coherent, intense beams of light. The beam can cause eye damage and instrument damage. There is enough power from the laser to ignite substances placed in the beam path, even at some distance. The beam might also cause damage if contacted indirectly from reflective surfaces (specular reflection). The laser on the GEN•S System is covered by a protective housing that is held in place by tamper-proof screws..

WARNING Possible harm to operator. Do not attempt to remove the laser or to open it. Failure to comply can result in hazardous radiation exposure. If removal is required, it must be done only by a Coulter Representative.

All service and maintenance of the laser must be done at the Coulter factory by trained personnel. If removal is required, it must be done by a Coulter Representative.

5.2 RADIATION HAZARDS

In the design and manufacture of the GEN•S System, Coulter Corporation has complied with the requirements governing the use and application of a laser as stipulated in regulatory documents issued by the

- U.S. Department of Health and Human Services, and
- Center for Devices and Radiological Health (CDRH).

In compliance with these regulatory documents, every measure has been taken to ensure the health and safety of users and laboratory personnel from the possible dangers of laser use.

5.3 LASER WARNING LABELS

WARNING Possible harm to operator. This instrument contains components dangerous to the operator. If any attempt has been made to defeat a safety feature, or if this instrument fails to perform as listed in this manual, disconnect power and call your Coulter Representative.

CDRH-approved labels are placed near or on those covers that, when removed, might expose laser radiation. Figure 5.1 shows the laser cover and the protective housing cut away. This illustration is intended only to show you what the system looks like, in compliance with CDRH. See Figure 5.1 for the labels and their locations on the laser head. See Figure 5.2 for the label location on the beam cover between the laser head and the sampling compartment. Figure 5.1 and Figure 5.2 show certification labels.

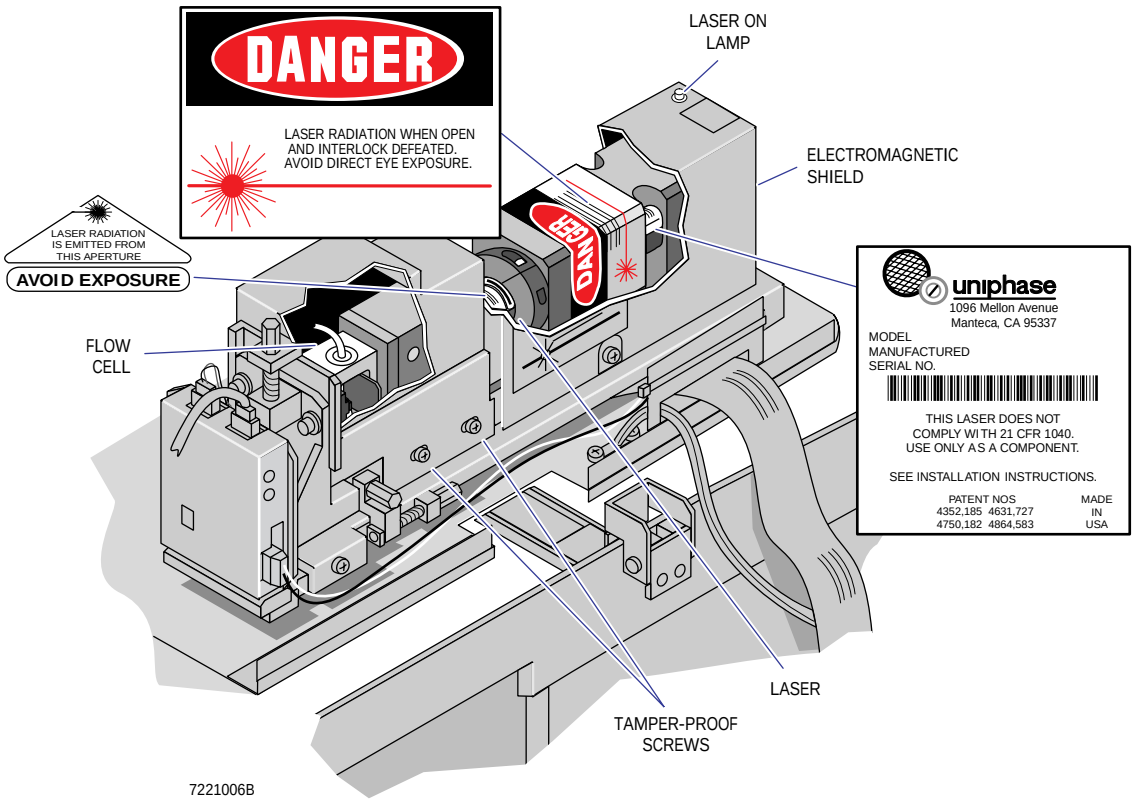

Figure 5.1 Laser Warning Label, Protective Housing Cut Away

Note: As installed in the Triple Transducer Module (TTM) safety fixture, the laser presents no radiation hazard to users and complies with 21 CFR 1040.

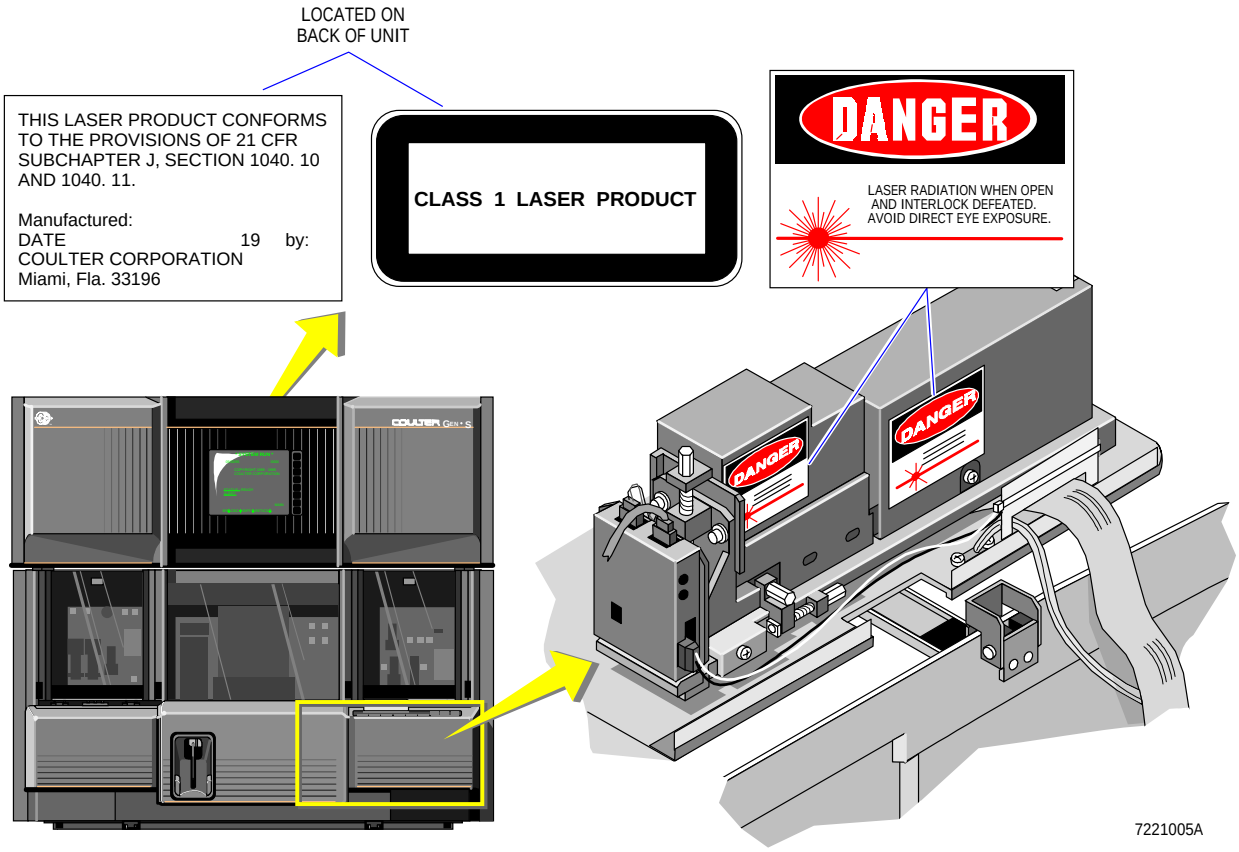

Figure 5.2 Laser Warning Label Locations, Protective Housing On

5.4 HANDHELD SCANNER

Figure 5.3 illustrates the label on the PSC® handheld scanner.

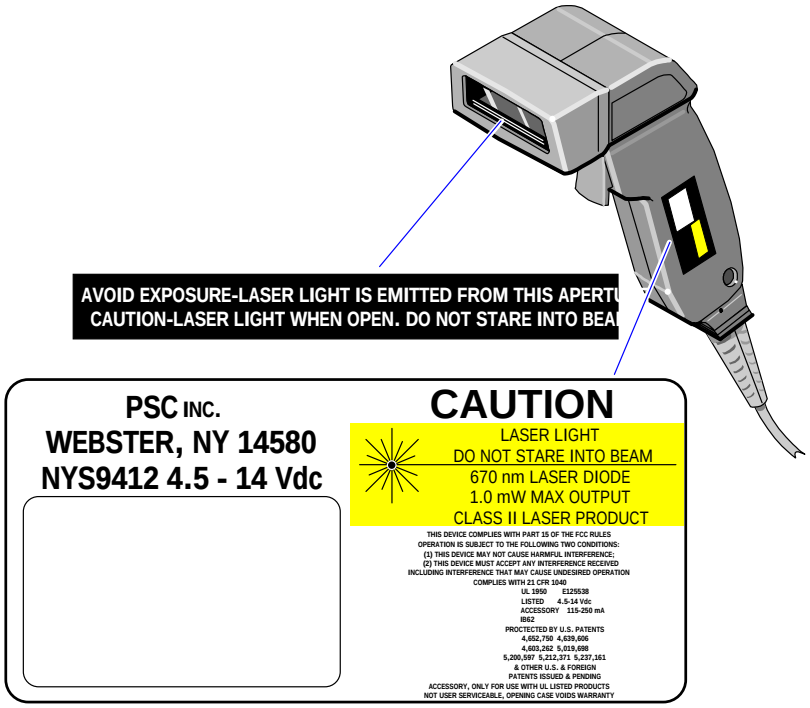
AVOID EXPOSURE-LASER LIGHT IS EMITTED FROM THIS APERTU
CAUTION-LASER LIGHT WHEN OPEN. DO NOT STARE INTO BEA
PSC INC.
WEBSTER, NY 14580
NYS9412 4.5 - 14 Vdc
CAUTION
LASER LIGHT
DO NOT STARE INTO BEAM
670 nm LASER DIODE
1.0 mW MAX OUTPUT
CLASS II LASER PRODUCT
THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES
OPERATION IS SUBJECT TO THE FOLLOWING TWO CONDITIONS:
(1) THIS DEVICE MAY NOT CAUSE HARMFUL INTERFERENCE;
(2) THIS DEVICE MUST ACCEPT ANY INTERFERENCE RECEIVED
INCLUDING INTERFERENCE THAT MAY CAUSE UNDESIRED OPERATION
COMPLIES WITH 21 CFR 1040
UL 1950 E125538
LISTED 4.5-14 Vdc
ACCESSORY 115-250 mA
IB62
PROCTECTED BY U.S. PATENTS
4,652,750 4,639,606
4,603,262 5,019,698
5,200,597 5,212,371 5,237,161
& OTHER U.S. & FOREIGN
PATENTS ISSUED & PENDING
ACCESSORY, ONLY FOR USE WITH UL LISTED PRODUCTS
NOT USER SERVICEABLE, OPENING CASE VOIDS WARRANTY

Figure 5.3 Handheld Scanner

REFERENCES

1. Coulter WH. High speed automatic blood cell counter and cell size analyzer. Paper presented at National Electronics Conference, Chicago, IL, 1956; October 3.
2. Brecher G, Schneiderman M and Williams GZ. Evaluation of electronic red blood cell counter. Am J Clin Path, 1956; 26:1439-1449.
3. Brittin GM, Brecher G and Johnson CA. Evaluation of the COULTER COUNTER Model S. Am J Clin Path, 1969; 52(6):679-689.
4. Gottman AW. Multiple hematologic analyses by means of a COULTER COUNTER Model S. Paper presented at International Symposium of Standardization of Hematological Methods, Fondazione, Carlo Erba, Milan, Italy, November 9 and 10, 1970. Symposium proceedings published in Haematologica Latina, 1969.
5. Hamilton PJ and Davidson RL. The interrelationships and stability of Coulter S-determined blood indices. J Clin Path, 1973; 26:700-705.
6. Bessman JD and Johnson RK. Erythrocyte volume distribution in normal and abnormal subjects. Blood, 1975; 46(3):369-379.
7. Price-Jones C. The diameters of red cells in pernicious anaemia and in anaemia following haemorrhage. J Path Bact, 1922; 25:487-504.
8. England JM, Walford DM and Waters DAW. Re-assessment of the reliability of the haematocrit. Brit J Haemat, 1972; 23:247-256.
9. Bull BS, Schneiderman MA and Brecher G. Platelet counts with the COULTER COUNTER. Am J Clin Path, 1965; 44(6):678-688.
10. Mundschenk DD, Connelly DP, White JG and Brunning RD. An improved technique for the electronic measurement of platelet size and shape. J Lab Clin Med, 1976; 88(2):301-315.
11. Schultz J and Thom R. Electrical sizing and counting of platelets in whole blood. Med Biol Engr, 1973; 73:447-454.
12. Von Behrens WE. Mediterranean macrothrombocytopenia. Blood, 1975; 46(2):199-208.
13. Paulus JM. Platelet size in man. Blood, 1975; 46(3):321-336.
14. International Committee for Standardization in Haematology. Recommendations for reference method for haemoglobinometry in human blood (ICSH Standard EP 6/2: 1977) and specifications for international haemiglobincyanide reference preparation (ICSH Standard EP 6/3: 1977). J Clin Path, 1978; 31(2):139-143.
15. Gauthier J, Harel P, Belanger C and Fraysse J. Human leukocytes: their size distribution and mean corpuscular volume. Can Med Assoc J, 1967; 97:793-796.
16. Hughes-Jones NC, England JM, Norley I and Young JMS. Differential leucocyte counts by volume distribution analysis. Brit J Haemat, 1974; 28(1):148.
17. England JM, Bashford CC, Hewer MG, Hughes-Jines NC and Down MC. A semi-automatic instrument for estimating the differential leucocyte count. Biomed Engr, 1975; 10(8):303-304.

18. Wycherley PA and O'Shea MJ. Abridged differential leucocyte counts provided by a Coulter Channelyzer in a routine haematology laboratory. J Clin Path, 1978; 31(3):271-274.

19. Oberjat TE, Zucker RM and Cassen B. Rapid and reliable differential counts on dilute leukocyte suspensions. J Lab Clin Med, 1970; 76(3):518-522.

20. Hoffman RA and Britt WB. Flow-system measurement of cell impedance properties. J Histochem Cytochem, 1979; 27(1):234-240.

21. Leif RC, Scwartz S, Rodriguez CM, Peel-Fernandez L, Groves M, Leif SB, Cayer M and Crews H. Two-dimensional impedance studies of BSA buoyant density separated human erythrocytes. Cytometry, 1985; 6(1):13-21.

22. Coulter WH et al. Signal modulated apparatus for generating and detecting resistive and reactive changes in a modulated current path for particle classification and analysis. US Patent 3,502,974, March 24, 1970.

23. Fulwyler MJ. Electronic separation of biological cells by volume. Science, 1965; 150:910-911.

24. Loken MR, Sweet RG and Herzenberg LA. Cell discrimination by multiangle light scattering. J Histochem Cytochem, 1976; 24(1):284-291.

25. Jovin TM, Morris SJ, Striker G, Schultens HA, Digweed M and Arndt-Jovin DJ. Automatic sizing and separation of particles by ratios of light scattering intensities. J Histochem Cytochem, 1976; 24(1):269-283.

26. Miale JB. Laboratory Medicine: Hematology. CV Mosby Company, St. Louis, MO, 4th ed., 1972; 22.

27. Corash L, Rheinschmidt M, Lieu S, Meers P and Brew E. Fluorescence-activated flow cytometry in the hematology clinical laboratory. Cytometry, 1988; Supplement 3:60-64.

28. Friedman EW. Reticulocyte counts: How to use them, what they mean. Diagnostic Medicine, 1984; 7(6):29-33.

29. Williams WJ, Beutler E, Erslev AJ, and Lichtman MA. Hematology. McGraw-Hill, Inc, New York, NY, 4th ed., 1990; 416.

30. Brecher G. New methylene blue as a reticulocyte stain. Am J Clin Path, 1949; 19:895-896.

31. Dorsey DB. What can quality control do for hematology? Am J Med Tech, 1965; Mar-Apr:150-153.

32. Bull BS. A statistical approach to quality control. Quality Control in Hematology, Symposium of the International Committee for Standardization in Haematology. Lewis SM and Coster JF, eds, Academic Press, London, England, 1975.

33. Koepke JA and Protextor TJ. Quality assurance for multichannel hematology instruments. Am J Clin Path, 1981; 75(1):28-33.

34. Bull BS. A statistical approach to quality control. Quality Control in Hematology, Symposium of the International Committee for Standardization in Haematology. Lewis SM and Coster JF, eds, Academic Press, London, England, 1975.

35. Eckhoff RF. An experimental indication of the volume proportional response of the Coulter Counter for irregularly shaped particles. J Sci Inst, 1967; 44:648-649.

36. Grover NB, Naaman J, Ben-asson S and Dojanski F. Electrical sizing of particles in suspension III. Rigid spheroids and red blood cells. Biophys J, 1972; 12:1099-1116.

37. Waterman CS, Atkinson EE, Wilkins B, Fischer CL and Kimsey SL. Improved measurement of erythrocyte volume distribution by aperture-counter signal analysis. Clin Chem, 1975; 21:1201-1211.

38. Kachel V and Ruhenstroth-Bauer G. Methodik and Ergebissne Optiseher Formfatorunter-suchungen bei der Zellvolumenmessung nach Coulter. Micros Acta, 1976; 75:419-423.

39. Bull BS, and Elashoff RM et al.: 1974. A study of various estimators for the derivation of quality control procedures from patient erythocytic indices. Am J Clin Path 61(4):475.

40. Koepke JA. Tips on technology. MLO:15, 1981.

41. Miale JB, Laboratory Medicine - Hematology. 3rd Edition 1967, CV Mosby, pages 592-595

A

Ampere, a unit of electric current.

Accuracy

Ability of the instrument to agree with a predetermined reference value.

Action Limits

Values established by your laboratory to flag results requiring action.

Algorithm

A particular procedure for performing an analysis.

Analytical Station

The Analyzer, Diluter, and Power Supply of the GEN•S System.

Analyzer Pulse

A graphical display on the Analyzer screen that indicates the condition of all the apertures. You can detect noise, bubbles, or a clogged flow cell by monitoring the pulses.

ANSI

American National Standards Institute.

Application

A computer program, generally started from a button or icon. For example the Patient Tests application.

ASCII

American Standard Code for Information Interchange.

Aspiration Mode

The method of running a sample, closed vial (Automatic aspiration mode) or open vial (Manual aspiration mode).

Assay Values

Values of all parameters for a control established by extensive assay of that control. These values are provided by the manufacturer of the control.

Also called: assigned values.

ASTM

American Society for Testing and Materials.

AutoCollation

A Workstation feature that automatically combines results of different test modes (CBC/Diff and Retic) analyzed from a sample with an identical patient or sample ID. The different test modes must be performed within a predetermined time.

Automatic Aspiration Mode

The closed-vial method of running a sample. You place a closed tube sample in a cassette and place the cassette on the GEN•S loading bay. The GEN•S System automatically reads the cassette label and tube label (if present) and aspirates the sample.

Also called: closed-vial mode, primary mode, automatic sampling mode.

Automatic Startup Cycles

Pressing START UP starts automatic startup cycles. When you press this button, the system flushes the cleaning agent from all Diluter components and tubing. It also performs electronic and fluidic checks to ensure the instrument is ready to analyze control or whole-blood samples. Specifically, the instrument:

- Performs reagent and waste level sensing.
- Replaces the cleaning agent with diluent.
- Performs a background count in the baths and flow cell.
- Measures Hgb-blank and Hgb-sample voltages.
- Performs ramp-pulse and precision-pulse tests.
- Performs an electronic check of the Triple Transducer Module (flow cell).

AutoNumbering

A Workstation feature that assigns a number to each sample received from the instrument.

Autopurge

If 24 hours elapse with the power on, pneumatics off, and the instrument in shutdown, the system automatically:

- Turns on the pneumatics.
- Drains and fills the baths.
- Purges the flow cell and associated sample lines with cleaning agent.
- Turns off the pneumatics.

During this process, the system displays messages, such as PERFORMING MINI PRIME and AUTOPURGE on the Diluter Keypad.

AutoSequencing

A Workstation feature used with the ToDo list to automatically increment the identifiers you specify (Cass/Pos, sample ID, and sequence number).

When you enter the sample ID, ensure you type the same number of digits as exist on your bar-code labels, including leading zeros.

AutoStop

A Workstation feature that instructs the instrument to stop processing based on specific criteria.

Average Value

A value that is computed by dividing the sum of a set of values by the number of values. Usually referred to as the simple arithmetic mean.

Background Count

A measure of the amount of electrical or particle interference using a diluent sample or no sample.

Background Results

Background results indicate reagent quality and the presence of electronic noise or bubbles. Background results above certain levels cause concern since they might falsely elevate (or interfere with) the results obtained for blood and control samples.

Batch

A group or set of results.

- For XB Analysis, a batch equals 20 patient samples used for monitoring MCV, MCH and MCHC as an automated QC procedure.
- For printing or transmitting, a batch equals the samples you selected from the database.

Batch Mean

The mean or average of a set of samples. For XB Analysis, the batch mean is a value based on a statistical averaging technique and is a type of "weighted moving average." It is used to estimate what a simple average result of a very large number of samples (population mean) might be by using a small number of samples.

Batch Print Job

Selecting multiple items from the database, then selecting the print button to print all of them at the same time.

Baud

A rate defining how many data bits per second are transferred during communications between two pieces of equipment.

Calibration

A procedure to standardize the instrument for accuracy by determining its deviation from calibration references and applying any necessary correction factors.

Calibration Disk

A data diskette containing the Assigned Values for the lot number of the S-CAL® calibrator kit being used.

Calibration Factors

Values the system uses to fine-tune instrument accuracy.

Carryover

The percentage or particle count (for Diff and Retic) of blood cells that are retained from one blood sample to the next.

Cassette Clips

Clips that you permanently install in each opening of the special cassettes for tubes with HEMOGARD™ Closure. These clips allow the special cassette to accommodate additional types of tubes.

CBC (Complete Blood Count)

A measure of the cell number and the indices. CBC includes WBC, RBC, Hgb, Hct, MCH, MCHC, Plt, MPV, and RDW.

CD4

Cluster Designation # 4.

A group based on monoclonal antibodies of similar molecular weight and protein composition. Monoclonal antibodies in a CD group tag or mark similar cells in similar ways. CD4 is expressed predominantly on the surface of T4 lymphocyte cells.

CD8

Cluster Designation #8.

A group based on monoclonal antibodies of similar molecular weight and protein composition. Monoclonal antibodies in a CD group tag or mark similar cells in similar ways. CD8 is expressed predominantly on the surface of T8 lymphocyte cells.

CDC

Centers for Disease Control and Prevention.

CEE

Commission for Electrical Equipment.

Cell Control

A preparation made of human blood with stabilized cells and surrogate material. It is used for daily instrument QC.

Characters

All letters A-Z and numbers 0-9.

Check Valve

A one-way valve that routes liquid or air through the Diluter.

Also called: mono-flow valve, one-way valve

CLIA

Clinical Laboratory Improvement Amendments.

cm

Centimeter, a unit of linear measurement.

Codes

On windows and printouts, symbols, such as **+++++** and – **– – – –** , that appear in place of sample or control results because of irregularities.

Coincidence

More than one cell within aperture-sensing boundaries at the same time. The system counts only one pulse and automatically corrects results for coincidence.

Collation

The process of combining the results of different test modes(CBC/Diff and Retic) analyzed from the same sample.

Command Center

A blue bar that appears at the bottom of the screen. It displays:

- Buttons that start the GEN•S System applications
- Instrument name and processing control fields that control what kind of data the Workstation expects to receive
- Bar-code ID for Manual aspiration mode
- Progress and system status indicators
- Last message posted to the history log that caused a stop condition
- Manual aspiration mode sample ID field.

Control Disk

A data diskette that contains the assay values for the lot number of the control being used.

COULTER FACULTY System

A computer program that uses the results from a COULTER instrument, demographic information, and supplementary test information to provide suggested follow-up testing and possible diagnoses.

Also called: knowledge-based system.

Coulter Principle

A method of counting and sizing cells by detecting and measuring changes in electrical resistance when a particle in a conductive liquid goes through a small aperture.

Critical Limits

Values established by your laboratory to flag results requiring immediate action.

CSA

Canadian Standards Association.

Cursor

On the screen, a place shown by a little blinking indicator or by a highlighted area. The cursor shows where you can select an option or type information.

CV (Coefficient of Variation)

An expression, in percent, of data spread as related to the mean.

%CV = (SD/Mean) x 100

Cycle Counter

A number that appears on the Analyzer MAIN MENU screen that represents the actual number of instrument cycles that have occurred.

Workstation

The computer hardware and software that controls instrument operation; displays, stores, and recalls sample data; automates QC and calibration procedures; and assists you in troubleshooting.

Also called: ADMS, DMS, GEN•S Workstation.

DataPlot

A graphic representation of results. DataPlots present a combined view of population density and membership. Colors represent different types of cells. Shades of colors represent the number of cells--bright colors are the most dense.

Default

A setting the instrument uses automatically. For example, you can set up a default printer. Every time you print sample results, the Workstation automatically prints the sample results to the default printer.

Definitive Messages

Definitive messages that appear for sample results based on numeric limits generated by your laboratory. If results exceed the limits, the Workstation generates a message. Results that generate these messages may require review. Check your laboratory's protocol for handling the particular message.

Delta Check

A check on sample results that is made by clinical laboratories to determine if the current result on a particular patient is within certain limits of the last result obtained on that same patient.

Density

The number of cells in a particular region, regardless of the type of cell.

On DataPlots, as more cells appear in a region, the color of the region gets brighter.

Diff (Differential)

Leukocyte differential parameters (NE, LY, EO, BA, and MO) and processes that relate to them.

The differential count for all parameters, when totaled, equals 100% except when ALL differential parameters display as zeros. If the differential count displays all zeros, check for additional flagging and take appropriate action according to your laboratory's protocol.

Digits

All numbers 0-9.

dL

Deciliter, a unit of volumetric measurement equal to 0.1 liter.

Double-click

UsingMeans

Light PenQuickly pressing the light pen against the screen twice.

Mouse Quickly pressing the left mouse button twice.

Touch ScreenQuickly touching the screen with your finger twice.

Drag

The process of selecting an item and maintaining the selection while you move the pointer to a different location.

EDTA

Ethylenediaminetetraacetic acid--the recommended anticoagulant for hematology analysis.

Expiration Date

A manufacturer's recommended last day of use for a reagent, control, or calibrator.

Field

Area on a window or screen for entering or viewing data. When you move the cursor, you are moving it from field to field.

fL

Femtoliter, a unit of volumetric measurement equal to 10^{-15} liter.

Flags

On windows and printouts, letters, such as H, L ,and R that appear next to parameter results to indicate specific conditions.

Flow Cytometry

A process for measuring the characteristics of cells or other biological particles as they pass through a measuring apparatus in a fluid stream.

Function Key

One of the keys labeled F1 to F12. To request a system or window-specific command, press the Function Key displayed on the screen next to the command. Sometimes these keys are used with other keys to access specific functions.

g

Gram, a unit of weight.

Hemoglobinometry

Measurement of hemoglobin in the blood. In the GEN•S System, this is done by comparing the amount of light that passes through a diluted lysed sample, in which the released Hgb has been chemically converted, with the amount of light that passes through a blank (ISOTON® III diluent).

Histograms (RBC & Plt)

Graphic representations of cell frequency vs. size. Histograms provide information about erythrocyte and thrombocyte frequency and their distribution about the mean. They also might show the presence of subpopulations.

Hz

Hertz, a unit of frequency.

i.d.

Inside diameter.

IEC

International Electrical Commission.

Information System

Any host or laboratory computer system.

Instrument

The Analyzer and Diluter portion of the GEN•S System.

IQAP (Interlaboratory Quality Assurance Program)

Coulter Corporation provides this program, which statistically compares your 5C® and Retic-C cell control data to a group of other laboratories' control recovery data with the same control lot number.

L

Liter, a unit of volumetric measurement.

Lab Administrator

A person at your location who can access the full set of Workstation functions. The lab administrator creates user names and assigns access levels. A specific user name and password is assigned to the lab administrator in your laboratory.

Laser (Light Amplification by Stimulated Emission of Radiation)

The instrument uses a laser for WBC Diff and Retic analysis.

Levey-Jennings Control Chart

A commonly used control procedure in which control measurements are plotted directly on a control chart with limit lines drawn as mean plus or minus expected ranges.

Linearity

The ability of an instrument to recover expected results (reference values or calculated values) for such parameters as WBC, RBC, Hgb and Plt at varying levels of concentration of these parameters within specified limits.

Coulter Corporation provides the LIN-C™ linearity control for your convenience. Use it according to the instructions on its package insert.

Lot Number

An identifier assigned by a manufacturer to identify a control, reagent or calibrator.

m

Meter, a unit of linear measurement.

Manual aspiration mode

The open-vial method of running a sample. You immerse the aspirator tip in the sample. The instrument automatically aspirates the sample. If the instrument fails to aspirate automatically, you can press and release the activator to aspirate the sample.

Also called: open-vial mode, secondary mode, manual sampling mode.

Manual Diff Box

A blank area included on a report where you can record your manual differential results for the sample.

Manual Print Job

Selecting the print button to print a single item.

Mean

Arithmetic average of a group of data.

Membership

The different types of cells in a particular region, regardless of the number of cells.

On DataPlots, membership is represented showing different types of cells in different colors.

mL

Milliliter, a unit of volumetric measurement, equal to 10^{-3} liter.

mm

Millimeter, a unit of linear measurement, equal to one-thousandth of a meter.

Mode-to-Mode Matching

Agreement between patient results in Automatic aspiration mode and Manual aspiration mode.

mW

Milliwatt, a unit of power equal to one-thousandth of a watt.

n

Number.

NCCLS

National Committee for Clinical Laboratory Standards.

NEMA

National Electrical Manufacturers Association.

nm

Nanometer, a unit of linear measurement, equal to 10^{-9} meter.

o.d.

Outer diameter.

Outlier

A data value far outside the range of the rest of the data.

Output Device

A physical device that is capable of receiving information from a computer and formatting it in a logical fashion. Examples: printer, fax machine or another computer.

Parameters

Characteristics of blood that the instrument measures and reports.

Parity

Method of detecting errors in data handling. The computer generates a parity bit such that the sum of the data bits for a data word are odd or even and stored in the parity bit for checking by the receiver of the data word.

Patient Population

A large number of patient sample results for XB Analysis, used to give a fairly consistent average result for each of the three red blood cell indices: MCV, MCH and MCHC.

pg

Picogram, a unit of gravimetric measure equal to one trillionth of a gram.

Photometric Measurement

A process where a beam of white light from an incandescent lamp goes through an optical filter and is read by a photocell. This generates a current that can be measured.

Plt Histogram

A Plt distribution curve. It displays only the area between 0 fL and 36 fL.

Positive Identifier

An identifier that is linked irrevocably to the date and time of instrument analysis on a sample and the sample results. A positive identifier must be entered before a sample analysis can occur. You can use either sample ID or Cass/Pos as positive identifiers of the sample and its results. You can also choose to use both sample ID and Cass/Pos as positive identifiers.

Precision

A measure of the ability of the instrument to reproduce similar results when a sample is run repeatedly. Precision of the instrument is a CV (or an SD for differential results), based on at least 31 replicate determinations of the same sample. Precision shows the closeness of test results when repeated analyses of the same material are performed.

Also called: reproducibility.

Precision Test

The precision test is performed as part of the automatic startup cycles. If any test value exceeds the reference value by 1% or more, the test value appears in red on the Workstation screen and is flagged with an H (high) or L (low). If an H or L flag appears:

1. Verify that clean diluent covers the apertures and that no bleach or cleaning agent is in the baths.
2. Repeat the precision test at the Analyzer.
3. If the flag recurs, call your Coulter Representative.

psi

Pounds per square inch, a unit of pressure measurement.

QC (Quality Control)

A comprehensive set of procedures your laboratory uses to ensure that the instrument is working accurately and precisely.

Ramp Test

The ramp test is performed as part of the automatic startup cycles. If any test value exceeds the reference value by 1% or more, the test value appears in red on the Workstation screen and is flagged with an H (high) or L (low). If an H or L flag appears:

1. Verify that clean diluent covers the apertures and that no bleach or cleaning agent is in the baths.
2. Repeat the ramp test at the Analyzer.
3. If the flag recurs, call your Coulter Representative.

RBC Histogram

An RBC distribution curve. The normal curve ranges from 36 to 360 fL. The display starts at 24 fL.

Record

A collection of related information, for example, sample identification and results information, stored in the database and treated as a unit.

Reflex Manager List

A list automatically generated by the Workstation based on sample result criteria set up by your laboratory. You can use this list as a management tool to allow automation of post-analysis decisions. As part of setting up the Reflex Manager List, you define the decision criteria and the follow-up action required.

Print Profile

A set of characteristics that define what you want printed and transmitted for sample runs. You can set up print profiles as part of System Setup.

Also called: Reports, Reporting Options

Reportable range

This range represents the clinical limits of values that have been tested and found to be accurate, precise, and linear. Reportable range can be the same as the linear range, but it is usually a subset of the linear range.

Reproducibility

A procedure to check that the system gives consistent results (within established limits) every time it measures the same sample. Also called: precision.

Sample ID

One of two possible positive identifiers for sample analysis. The other possible positive identifier is Cass/Pos.

For Automatic aspiration mode, this identifier is read from the bar-code label of the sample. For samples using Manual aspiration mode, this is the identifier specified at the Diluter Keypad or read from the bar-code label on the sample by using the wedge scanner.

Screen Saver

The Workstation has a screen saver that appears when you are not interacting with the Workstation. You can set up the screen saver to appear at specific intervals of non-use.

The screen returns to its normal view when the Workstation receives sample data or when you interact with the Workstation by pressing a key on the keyboard, touching the screen or using the light pen.

SD (Standard Deviation)

A measure of deviation from the mean.

$$SD = \sqrt{\frac{\Sigma(x - \bar{x})^2}{n - 1}}$$

Shift

1) Consecutive values that abruptly move from one side of the mean to the other, then maintain a constant level. Contrast with trend. 2) A scheduled period of work.

Status Bar

A horizontal bar that appears toward the bottom of the screen. It displays short instructions that can help you work with the GEN•S Workstation. It also displays information about various GEN•S options.

Stop Bit

A computer code that indicates the end of a character.

Suspect Messages

Suspect messages appear for sample results based on an abnormal cell distribution or population. The system generates these messages according to an internal algorithm. Abnormalities should be confirmed by microscopic review.

Sweep Flow

A steady stream of diluent that flows behind the RBC aperture during sensing periods to keep RBCs from swirling back into the sensing zone.

Test (Modes)

At the Analyzer, you specify the test mode. It determines how the GEN•S System processes data. The GEN•S System has the following test modes:

CBC	Performs basic complete blood count on whole-blood samples.
Retic	Performs Retic analysis on whole blood samples.
CBC/Diff	Performs complete blood count and WBC differential on whole-blood samples.

CBC/Retic Performs basic complete blood count and Retic analysis on whole-blood samples.

CBC/Retic/Diff Performs basic complete blood count, WBC differential, and Retic analysis on whole-blood samples.

The test mode appears as a field on the QA Results & Graphics window.

ToDo List

A feature of the Workstation that lets you view a list of samples the instrument has not yet processed. You can view a list of all the unprocessed samples or a list of unprocessed samples for a particular test mode. You can sort these lists by any column you choose.

Also called: Worklist, Pending List, Work Order.

Toolbar

A group of graphic buttons on a Workstation window. You can select a button on a Toolbar to quickly access commonly used functions.

Trend

Values that continue to increase or decrease gradually over a period of time. Contrast with shift.

Tube Adapters

Special holders that enable small tubes to fit in standard cassettes. Two sizes of gray sleeve adapters accommodate 2.0-mL tubes and 3.0-mL tubes.

UL

Underwriters Laboratory.

User Name

A 16-character identifier that uniquely identifies the processor of the samples. If you forget your user name or password, contact your lab administrator. The user name works with your password to uniquely identify you to the system.

Also called: operator ID.

Vac

Volts of alternating current.

VCS (Volume, Conductivity and Scatter)

A flow cytometry technology applied in hematology to enhance WBC subpopulation classification and percent Reticulocyte measurement.

Voting

After the computer corrects for coincidence, it compares the three count periods. Voting may occur for WBC, RBC, Plt, MCV, RDW and MPV. Agreement among the three count periods causes them to be averaged to determine the parameter result.

If the instrument finds disagreement among all three count periods, the Workstation displays the total voteout code, – – – – –, instead of the parameter result.

W

Watt, a unit of power.

WBC Threshold Monitor

A WBC distribution curve. The WBC histogram displays a visual representation of interference around the 35 fL threshold. A marker appears at the threshold to help you determine the degree of particle interference.

Window

A rectangular area on your computer screen that enables you to work with an application.

Windows NT™ Workstation Operating System

The Microsoft® operating system for your computer.

XB Analysis

A method of quality control that automatically compares patient red blood cell indices (MCV, MCH and MCHC) with known target values. It is used to monitor for proper operation of automated instruments in hematology.

µL

Microliter, a unit of volumetric measurement equal to one millionth of a liter.

µm

Micrometer, a unit of linear measurement equal to one millionth of a meter.

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TRADEMARKS

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▪ Host Transmission PN 4237306	Specifications for transmitting to a host computer
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